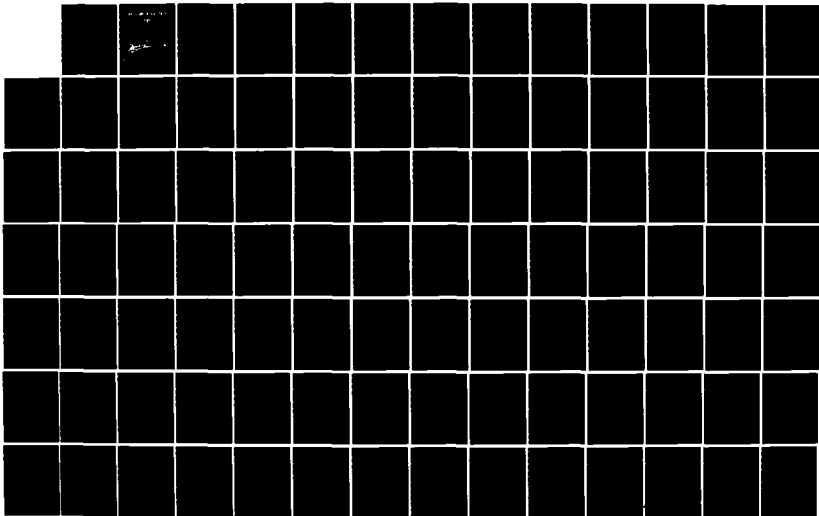


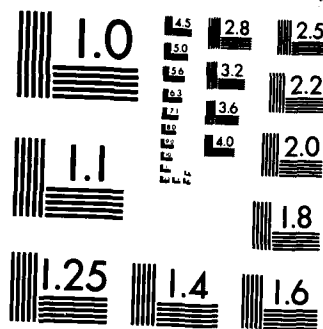
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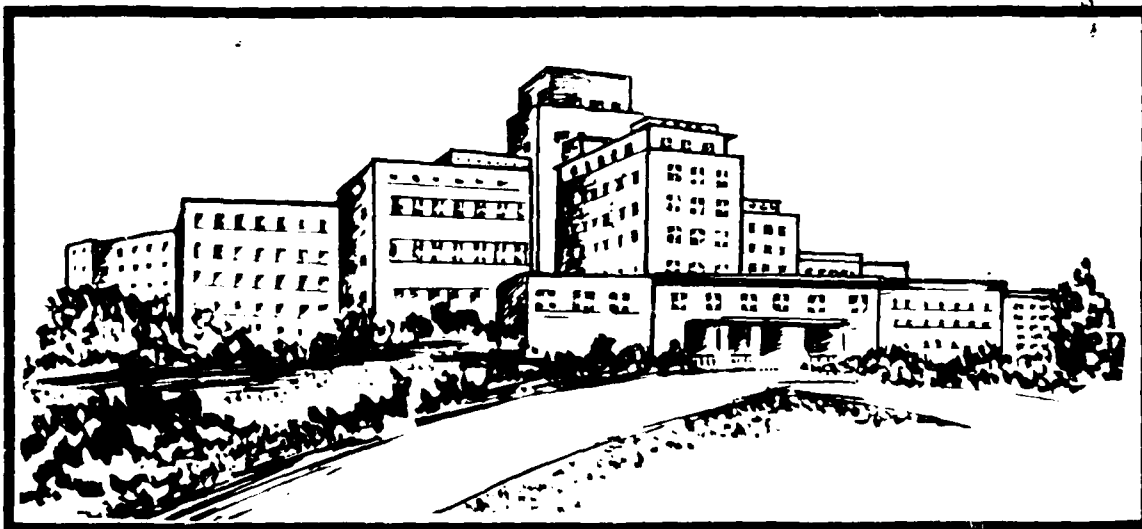




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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical investigation; experimental projects; research projects; in-house research; publications, presentations of research data; project status; experimental design.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each project giving abbreviated technical objectives, methods, and progress is presented. <i>Investigations were conducted by the following Departments:-</i>		

ANNUAL PROGRESS REPORT

CLINICAL INVESTIGATION PROGRAM
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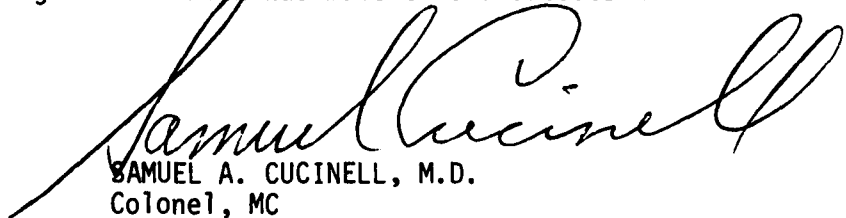
FOREWORD

Contained herein are progress reports on research projects fostered by the Clinical Investigation Program at Tripler Army Medical Center (TAMC) during Fiscal Year 1984.

The human research has been approved by the Clinical Investigation and Human Use Committees of TAMC in accordance with Army Regulations and Federal Law. In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care" as promulgated by the National Academy of Sciences/National Research Council, the criteria established by the American Association for Accreditation of Laboratory Animal Care, and the principles embodied in the Declaration of Helsinki.

This Annual Progress Report contains publications, presentations, awards, proposals, preliminary findings, unit staffing, and fiscal data.

We thank MG Tracy E. Strevey, Jr., MD, MC and his staff for their attention to our small and large needs which has made this a successful year.



SAMUEL A. CUCINELL, M.D.

Colonel, MC

Chief, Dept of Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: The mission of the Department of Clinical Investigation is to support scholarly research by the physicians and staff at TAMC. We give this the narrow but concrete interpretation of producing published manuscripts. The number of published papers was 49 in 1984, an increase of 8 from 1983 (Fig. 1). Despite the goal of increased publications, the main workload is administration and assuring TAMC's compliance with all laws, Army regulations, and social demands on research. This translates into more strict documentation of all we do. This added burden on research is no different from the administrative burden in all of medicine.

B. TECHNICAL APPROACH: This year the additional administrative burden is the documentation of all gifts. All research projects must include the identification of gifts of every nature, and the hospital must account for these gifts. The Department of Clinical Investigation Annual Progress Report for 1984 identifies all known gifts and the projects that they supported. This is only partially complete since recording of this information did not start until July of 1984. Also we must document a "course" in clinical research. Certain residency programs require a formalized course in research technique and this four session course is intended to meet that requirement.

C. STAFFING:

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Cucinell, Samuel A.	COL	61F9B	Chief
Askew, Eldon W.	LTC	68C9B	Chief, Biochemistry Service
Lieberman, Michael M.	MAJ	68A9C	Chief, Microbiology Service
Stokes, William S.	CPT	64C9B	Chief, Veterinary Service
Coussens, Wayne R.	CPT	68T9B	Research Psychologist
Banks, Ronald L.	SFC	92B40	NCOIC
Frank, William J.	SP5	01H20	Biological Science Asst
Bemis Joseph L.	SP4	91T10	Animal Specialist
Gooch, Gordon H.	SP4	92B10	Medical Laboratory Specialist
Reese, Jamie B.	SP4	91T10	Animal Specialist
Penrose, Tammie J.	PFC	91T10	Animal Specialist
Claybaugh, John R.	GM14	00413	Chief, Physiology Service
Bryant, Gordon H.	GS11	00802	Biomedical Engineer
Hashiro, Glenn M.	GS09	00404	Biological Laboratory Tech
Sato, Aileen K.	GS09	00404	Biological Laboratory Tech
Sondeen, Jill L.*	GS07	00404	Biological Laboratory Tech
Masunaga, Lois E.	GS07	01087	Editorial Assistant
Armann, Shirley A.	GS04	00312	Clerk-Steno
Carroll, Kenneth J.*	GS04	00404	Biological Aide
Dice, Margaret S.*	GS04	00404	Biological Aide (Part-time)
Albert, Thomas G.	WG04	03566	Animal Caretaker

*On USAMRDC grant

D. FUNDING:

Funding Type	1980	1981	1982	1983	1984+
Civilian personnel including benefits	\$151,461*	\$167,320*	\$231,799	\$237,032	\$257,145
Consumable supplies	78,986	65,783	89,128	84,373	129,563
Civilian contracts including consultants	3,047	1,694	10,406	6,231	16,455
TDY	16,181	16,877	18,272	20,857	23,316
Publications	1,623	1,900	3,543	2,213	4,166
Noninvestment equipment (Minor MEDCASE)	651	1,448	16,256	1,248	8,230
Trans & Taxes	409	213	143	1,481	63
Other OMA Rentals	7,587	1,510		8,309	
OMA Total	259,945	256,745	369,547	361,744	438,938
MEDCASE	41,370	85,594	64,617	24,000** 54,423	107,500
Military	220,999	247,946	302,016	333,850	330,352
TOTAL	\$522,314*	\$590,285*	\$736,180	\$774,017	876,790

*Two employees not included

**BLIC R

+Includes USMRDC Grant

E. PROGRESS: Although very modest for the work done, the members of the administrative staff of DCI have been recognized; Mrs. Lois Masunaga, editorial assistant, was given an exceptional performance award; Mrs. Shirley Armann, clerk-stenographer, exceptional performance and special act award; Ronald Banks, NCOIC, has been promoted to Sergeant First Class and Wayne Askew, Deputy Chief, was promoted to Lt Colonel.

The Department of Clinical Investigation has had no major setbacks in 1984 and some successes. The department carried out its second high altitude study. This complex effort was carried out with personnel from the Department of Pediatrics and Directorate of Logistics at TAMC, as well as scientists from LAMC, LAIR, and USAMRIID. The support of the Commanding General, TAMC, WESTCOM Surgeon's office, and the Commanding General, WESTCOM were critical. The study was carried out with such precision that the first data from it was

presented by LTC Wayne Askew to the National Science Foundation meeting on nutrition in Washington two weeks after the descent.

CPT Stokes, Chief of the Veterinary Service, coordinated the demanding engineering, personnel, and professional details needed to retain full AAALAC accreditation at TAMC. He also was consultant to HSC in meeting the challenge of prohibition of dog and cat research in all Army programs. Fortunately, this policy has been reversed.

Individual successes were as follows: the first patent ever granted to a member of the TAMC staff was received by Mr. Gordon Bryant, who was nominated for the Commander's Award. Dr. John Claybaugh was recognized with an outstanding rating by the Merit Committee of HSC. CPT Wayne Coussens was awarded a grant by the USAMRDC for the study of intellectual function at high altitude. The following enlisted personnel were recognized: SP5 William Frank as Soldier of the Month; Jamie Reese and Gordon Gooch were promoted to SP4, and Tammy Penrose to PFC.

We regret the departure of SP4 Joseph Bemis, who has left the Army to prepare for a career as a medical or veterinary physician.

F. PROBLEMS: In 1985 CPT Coussens and LTC Askew will be leaving. The administrative workload will not decrease to meet the loss of personnel.

Figure 1

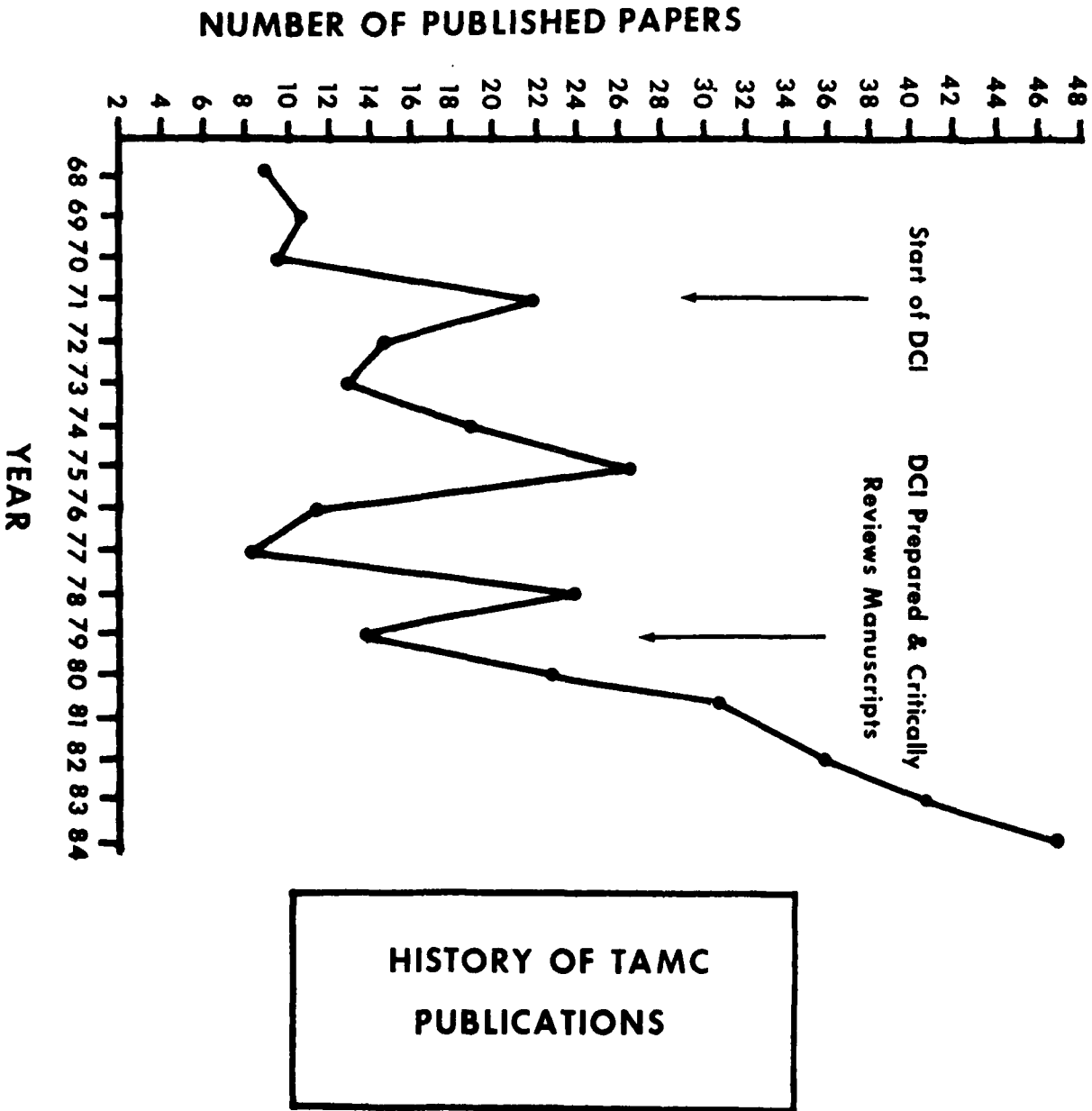


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Miyazawa K: Use of Laparoscopy in Gynecologic Oncology. Postgraduate Course "Advanced Laparoscopy," American Association of Gynecologic Laparoscopists, January 1984

Miyazawa K: Hysteroscopy in Abnormal Uterine Bleeding. Postgraduate Course "Hysteroscopy, Principle and Practice," American Association of Gynecologic Laparoscopists, January 1984

Miyazawa K: Contact Hysteroscopy. Postgraduate Course "Hysteroscopy, Principle and Practice," American Association of Gynecologic Laparoscopists, January 1984

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Miyazawa K: GU and GI Complications in Pelvic Surgery. 32nd Annual Clinical Meeting of ACOG, May 1984

Miyazawa K: Use of Gynecologic Endoscopy in a Military Teaching OB-GYN Department. Japanese Congress of Obstetricians & Gynecologists, August 1984

Shaw CT, Osterholzer HO, Swan HS: Jackson-Pratt Drainage, Cefamandole Nafate Irrigation, Alone and in Combination, as a Method to Reduce Postoperative Vaginal Cuff Cellulitis in Patients Undergoing Abdominal Hysterectomy. Armed Forces ACOG District Meeting, October 1983

DEPARTMENT OF PEDIATRICS

Bass JW: Guest Faculty, 3rd Annual Critically Ill Child Symposium. Pulmonary Infections in the ICU; Life Threatening Infection in the ICU; Septic Shock. St. Joseph's Hospital Medical Center, Phoenix, AZ, February 1984

Bass JW: Guest Faculty, American Academy of Pediatric CME Course on Pediatric Infectious Diseases. Streptococcal Pharyngitis; Infectious Diarrhea; Croup and Epiglottitis. Lahaina, Maui, HI, April 1984

Bass JW: Guest faculty, Tropical Medicine Course. Pertussis; Streptococcal and Hemophilus influenzae Infections. Walter Reed Army Institute of Research, Washington, DC, August 1984

Bass JW: Consultant and Lecturer in Pediatric Infectious Diseases. Zama, Yokota, Yokosuka American Military Hospitals. Streptococcal Pharyngitis: New Developments; Croup and Epiglottitis; Infectious Diarrhea. Tokyo, Japan, August 1984

Enzenauer RW, Wiswell TE, Powell JM, Bass JW: Decreased Circumcision Rate with Videotape Counseling. APS/SPR Annual Meeting, San Francisco, CA, May 1984

Krober MS, Bass JW, Michels GN: Effectiveness of Penicillin for Treatment of Streptococcal Pharyngitis. 19th Annual Uniformed Services Pediatric Seminar, Reno, NV, March 1984 (C)

Krober MS, Bass JW, Powell JM, Smith FR: Fever in the First Three Months of Life: Bacterial and Viral Agents. 19th Annual Uniformed Services Pediatric Seminar, Reno, NV, March 1984 (C)

Rawlings JS: Prenatal Care and Prematurity. American Academy of Pediatrics, Chicago, IL, September 1984

DEPARTMENT OF RADIOLOGY

Chacko AK: Review of the Thyroid Carcinoma Experience at Tripler Army Medical Center. 2nd Annual Shogun Medical Society Meeting, Tokyo, Japan, April 1984

Chacko AK: Radionuclide Thyroid Angiography. 2nd Annual Shogun Medical Society Meeting, Tokyo, Japan, April 1984

Chacko AK: Radionuclide Thyroid Angiography - Review of a Five-Year Study. European Nuclear Medicine Congress, Helsinki, Finland, August 1984

DEPARTMENT OF SURGERY

Everton DM: Autologous Fascia Implant. Southern Section, American Academy of Facial Plastic and Reconstructive Surgery, Marco Island, FL, January 1984 (C)

Hornback CF, Reinker KA: Scoliosis in Identical Twins. 47th Annual Meeting, Western Orthopaedic Association, October 1983

Linsenmeyer TA, Rogers BJ, Soderdahl DW: The Effect of Clomiphene Citrate on Sperm Concentrations and the Sperm Penetration Assay in Oligospermic Infertile Males. Kimbrough Urological Seminar, San Francisco, November 1983 (Honorable Mention) (C)

Quilligan JJ: External Rhinoplasty Approach to Transsphenoidal Hypophysectomy. Western Section, American Academy of Facial Plastic and Reconstructive Surgery, Los Angeles, CA, January 1984

Reinker KA, Davis JS: Blount's Disease--A Reappraisal. 47th Annual Meeting, Western Orthopaedic Association, October 1983

Soderdahl DW.: Monitoring of Suspected Infertile Men with Varicocele by the Sperm Penetration Assay. Annual Meeting, American Urological Association, New Orleans, LA, May 1984

PHARMACY SERVICE

Solimando D: Preparation and Administration of Antibiotics and Chemotherapy Drugs. Depts of Pharmacy and Nursing, Hilo Hospital, Hilo, HI, February 1984

Solimando D: Safety Precautions in Handling Parenteral Medications. Hawaii Society of Hospital Pharmacists, Honolulu, HI, July 1984

Detail Summary Sheet

Date: 7 Nov 84 Prot No: 12/83 Status: Completed
 TITLE: A New Method for Obtaining Repeated Blood Samples in the Rabbit

Start Date: Mar 83		Est Comp Date: Sep 84
Principal Investigator: SP4 Joseph L. Bemis		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Veterinary		Associate Investigators: CPT William S. Stokes, VC
Key Words: Rabbit Blood sample		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1000.	Periodic Review Results: Completed

OBJECTIVE: To investigate the possibilities of a safe and reliable technique for repeated collections of a large blood sample in the conscious rabbit.

TECHNICAL APPROACH: The project was conducted using 20 unanesthetized rabbits. The first 10 rabbits were put in a rabbit-restraining device and 5 ml of blood was withdrawn 3 times daily using marginal ear vein or central artery of the ear. The remaining 10 rabbits were held by a different restraining device that enables easy access to the rear legs. With the rear legs exposed, 5 ml blood samples were withdrawn using the saphenous vein. In both groups of rabbits, blood samples were withdrawn 3 days a week for a period of 3 weeks.

PROGRESS: It was found in the first 10 rabbits that 5 ml of blood withdrawn 3 times a day could not be accomplished by using both the marginal ear vein and the central artery of the ear. In the 10 remaining rabbits, samples were obtained using the lateral saphenous vein. A total of 27 blood samples were collected from each rabbit. Each time, the full 5 ml of blood was obtained from one venipuncture site. Each sample took approximately 15 to 30 seconds to obtain. No clotting was observed in any sample. Up to 18 consecutive blood samples were collected from the same vein. One rabbit was bled using the same vein for all 27 venipunctures. Mean packed-cell volumes decreased 5.4% in the 3-week period from 36.4% to 31.0%.

Presentation: A New Method for Repeated Venous Blood Sampling in the Conscious Rabbit. 35th Annual Session, American Association for Laboratory Animal Science, Cincinnati, Ohio, 1984.

Detail Summary Sheet

Date: 9 Nov 84	Prot No: 34/79	Status: Ongoing
TITLE: Fabrication of a Catheter for the Determination of Liver blood Flow in Dog and Man		
Start Date: Oct 79	Est Comp Date: Sep 84	
Principal Investigator: Gordon H. Bryant	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation	Associate Investigators: COL Samuel A. Cucinelli, MD CPT William S. Stokes, VI	
Key Words: Liver blood flow		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3500.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: The development of a catheter fulfilling the purpose described in the title has been achieved but lacks the appropriate levels of accuracy. The objective of this project is therefore amended to secure an improvement in accuracy.

TECHNICAL APPROACH: Blood/injectate mixing, injectate heat gain, flow variability and baseline errors are some of the factors that have been identified as sources of erroneous results in the course of this study resulting in improvements in technique and results obtained.

PROGRESS: Limiting quantity of negative calories injected to 50, phase inversion of one of the thermal dilution curves and retrograde injection are some of the steps taken resulting in reduction of heat gain, baseline errors and mixing, thus enhancing accuracy which is expected to improve further following additional studies.

Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. 31st Annual Session, American Association for Laboratory Animal Science, Indianapolis, IN, Oct 1980.

Hepatic Venous Blood Flow in Shock by Thermal Dilution Technique. Ann Mtg, FASEB, Atlanta, GA, Apr 1981.

Bryant GH, Cucinelli SA, Goodwin BS: Measurement of Hepatic Venous Blood Flow in Shock by Thermal Dilution. Proc West Pharmacol Soc 24:23, 1981.

Bryant GH, Cucinelli SA: Hepatic Blood Flow by Multiple Thermistor Catheter Thermodilution Technique. Fed Proc 41(5):1703 (Abs #8378, Mar 1982.

Bryant GH, Cucinelli SA: Factors Affecting Heat Exchange in the Inferior vena Cava. Submitted to J Surg Res.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: 14/83 Status: Ongoing
 TITLE: Liver Blood Flow/Cardiac Output by Electrolytic Conductivity

Start Date: Jan 84		Est Comp Date: Jan 86
Principal Investigator: Gordon H. Bryant		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation		Associate Investigators: COL Samuel A. Cucinell, MC
Key Words: Liver blood flow Cardiac output		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$750.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To compare accuracy obtainable by injection of hypertonic saline and recording of resulting change in electrical conductivity in the blood vessel above and below the hepatic veins or in the pulmonary artery as an alternative to thermal dilution (TD).

TECHNICAL APPROACH: Injection of 37°C hypertonic saline and measurement of conductivity change giving curves similar to those of thermodilution will be attempted as a method of eliminating heat gain and temperature measurement errors inherent in the TD technique.

PROGRESS: Preliminary studies in a model showed that conductivity of blood is high when close-spaced electrodes are utilized and the change is small when 5% saline is mixed with the blood. Problems of standardization need to be met and special apparatus fabricated or purchased to pursue this study which has the merit of eliminating the primary source of error in the TD technique.

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 22/80 Status: Ongoing

TITLE: Antidiuretic Hormone Secretion in the Asphyxiated Neonate

Start Date: Aug 80	Est Comp Date: Mar 86
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology	Co-investigator: CPT Stephen R. Pratt
Key Words: Antidiuretic hormone; asphyxiated neonate; cerebrospinal fluid; urine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,000.
	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To determine the physiologic response of antidiuretic hormone (ADH) secretion in cerebrospinal fluid (CSF) and plasma in the newborn infant who has experienced central nervous system (CNS) injury, hypoxemia and asphyxia, i.e., is there evidence for independent control of release of ADH into the CSF and plasma. Also, to test the hypothesis that hypoxemia will increase release of ADH into the CSF and consequently lead to increased pressure in the CSF or other evidence of cerebral edema.

TECHNICAL APPROACH: Subjects will be neonates admitted for evaluation of sepsis, as well as all newborn infants with intracranial hemorrhage, CNS injuries from birth trauma, and neonates experiencing severe asphyxia with hypoxemia, increased intracranial pressure, and cerebral edema. On admission, each patient's APGAR scores, temperature, heart rate, blood pressure, and weight will be recorded. Arterial blood gases will be evaluated for acidosis, hypoxemia, and oxygen requirement. Spinal fluid will be collected for ADH assay, Na⁺ and K⁺ concentration, and osmolality. Urine will be assessed for creatinine, Na⁺, K⁺, osmolality, and ADH concentration. The data collected will be assessed to determine the correlation of CSF ADH and urinary ADH excretion and the correlations of both of these parameters to known stimulators of ADH release, i.e., plasma osmolality (if available), CSF osmolality, body temperature, and arterial blood pressure and PaO₂ and PaCO₂. If computerized axial tomography scans are performed, an attempt will be made to correlate cerebral edema with high CSF ADH levels.

PROGRESS: To date, 22 neonates have been assessed for CSF ADH concentration. Of those, 20 have had sufficient blood gas analysis for preliminary statistical work-ups. Results are as yet statistically insignificant, although tendencies are evident. Increased arterial pH, PO₂, and APGAR scores are associated with decreased CSF ADH concentrations. It is expected that 40 to 60 more patients would be sufficient to complete this study. In another project, we have established "normal" urinary ADH excretion rates for neonates. CPT Stephen R. Pratt has agreed to conduct the clinical aspects of the study.

Detail Summary Sheet

Date: 31 Dec 84	Prot No: 25/80	Status: Ongoing
TITLE: Urinary Metabolites of Vasopressin: Consequences in Radioimmunoassay		
Start Date: Aug 80	Est Comp Date: Sep 85	
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: Aileen K. Sato	
Key Words: Vasopressin; renal metabolism; antidiuretic hormone		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$6000.	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To determine if a biologically inactive but immunologically detectable metabolite constitutes a significant amount of the vasopressin molecule excreted in the urine.

TECHNICAL APPROACH: Vasopressin has been shown to be metabolized in the renal nephron of some animals. We have analyzed vasopressin with two antisera that we have characterized as being specific to the "tail" or "ring" portion of the vasopressin molecule. Urine will be fractionated by various methods. If two chemical identities can be shown that have immunological activity with one antibody but not the other, our results would clarify the need to use a specific type of vasopressin antisera. Our hypothesis is that this is the case, and that a "ring"-directed antibody detects more of the filtered vasopressin than a "tail"-directed antibody, and is therefore essential for the most accurate assessment of urinary vasopressin in excretion.

PROGRESS: Human, pig, rat, and dog urine contain immunologically detectable vasopressin measured by both "tail" and "ring"-directed antibodies. Using HPLC, we have identified two immunologically active peaks. Also, we have found 3 H phe-vasopressin is identifiable in the same two peaks. The obvious possible metabolites, i.e., des-gly AVP; des-gly, des-arg AVP; and des-gly, des-arg, des-Pro AVP have been ruled out. We have not achieved isolation of the material. We have learned that extraction of urine with octadecylsilane will eliminate this non-vasopressin substance, and presently, until further characterization is obtained, we will extract human urine prior to assay.

Claybaugh JR, Sato AK: Identification by high performance liquid chromatography of the immunologically detectable peaks of vasopressin activity in human urine. Fed Proc 42:1116, 1983 (Abstract 4829).

Claybaugh JR, Sato AK: Factors influencing urinary vasopressin concentration. Fed Proc (Manuscript in press).

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 5/82 Status: Terminated
 TITLE: Splanchnic Clearance of Vasopressin

Start Date: Jan 82		Est Comp Date:
Principal Investigator: John R. Claybaugh, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec; Clinical Investigation/Physiology		Associate Investigators: COL Samuel A. Cucinell, MC COL Peter Barcia, MC CPT William S. Stokes, VC Gordon H. Bryant
Key Words: Vasopressin clearance Liver Splanchnic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2,000.	Periodic Review Results: Terminated

OBJECTIVE: To determine where in the splanchnic circulation vasopressin is metabolized.

TECHNICAL APPROACH: Six pigs will be employed. They will be anesthetized with sodium pentobarbital and sacrificed at the end of the experiment. The animals will be surgically prepared to provide access to hepatic portal vein, arterial, and hepatic vein samples. In addition, thermodilution probes will be surgically positioned above and below the hepatic veins in order to assess hepatic blood flow by previously published techniques. In addition, the bladder will be cannulated to obtain urine samples. Then, hepatic clearance, $[(\text{portal vein}_{[\text{vasopressin}]} - \text{hepatic vein}_{[\text{vasopressin}]}) \times \text{hepatic blood flow}]$, and renal clearance, $[\text{urine}_{[\text{vasopressin}]} \times \text{urine flow rate} \div \text{arterial}_{[\text{vasopressin}]}]$, can be determined. In addition, fairly accurate assessment of splanchnic and splanchnic-hepatic clearances can be determined.

PROGRESS: Contrary to previously published interpretations that the liver is responsible for upwards of 50% of total vasopressin metabolism, our preliminary results (two animals) indicate that the liver plays a minor role in the splanchnic clearance of vasopressin. However, the splanchnic clearance of vasopressin without the liver is significant. More animals must be run to substantiate these findings, and further experimentation must be conducted to determine where in the splanchnic circulation this metabolism occurs. Another laboratory, i.e., Dr. L. Share, has recently published similar findings to our preliminary findings. The animal was the dog. A reassessment of available data and methods should be made before redesign of a new protocol.

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 25/83 Status: Completed

TITLE: Mechanism of Exercise Dehydration at Altitude

Start Date: Jul 84		Est Comp Date:
Principal Investigator: John R. Claybaugh, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology		Associate Investigators: COL S.A.Cucinell, MC; MAJ E.W. Askew, MSC; CPT W.R.Coussens, MSC; CPT W.S.Stokes, VC; Charles Wade, Ph.D.; Rudolph Dressendorfer, Ph.D.; CPT Charles Watson, MSC
Key Words: Exercise Altitude		
Accumulative MEDCASE Cost: \$57,000.	Est Accumulative OMA Cost: \$50,000.	Periodic Review Results: Completed

OBJECTIVE: This study was phase II of a two-part study. We investigated the physiological, psychological, and nutritional responses of continuous long-distance running, 2 hrs/day, for seven consecutive days. During phase I we investigated these parameters at sea level. During phase II we studied the same parameters at an altitude of 7,000 feet. The specific objectives of doing these studies at high altitude are based on the known effects of high altitude on fluid and electrolyte balance, cognitive processing, and various degrees of anorexia. Similarly, these factors are influenced by exercise. The combination of high altitude and strenuous exercise is a real possibility in the deployment of Army personnel.

TECHNICAL APPROACH: Fifteen men were selected from military volunteers. The men were divided into two groups. One began the daily runs of 2 hours immediately after arrival at high altitude, and the other was given a 2-day rest period at high altitude before beginning their daily running. The men were assigned to groups 1 and 2 in a manner that roughly balances the relative fitness of the two groups as determined by sea level, VO_2 max, and skinfold measurements. Intermittently before, during, and after the high altitude training, measurements were taken to determine salt and water balance, various hormonal patterns, motivation and cognition, and nutritional status, including various enzyme concentrations.

PROGRESS: Support was received from USAMR&DC on the study.

Claybaugh JR, Sondeen JL, Smith FR, Young AD, Wade CE, Cucinell SA, and Askew EW: Hormonal and Water Balance Responses to Seven Days Training at Sea Level and 2200 M in Men. Fourth International Hypoxia Symposium, Lake Louise, Alberta Canada, February 1985.

Askew EW, Szeto EG, Hashiro GM, Young AJ, Claybaugh JR, and Cucinell SA: Nutrient Intakes During Seven Days of Exercise at 2200 M Altitude. Fed Proc 1984 (Abstract).

Detail Summary Sheet

Date: 21 Dec 84 Prot No: 26/83 Status: Completed
 TITLE: Urinary Excretion of Vasopressin in the Newborn

Start Date: Jun 83		Est Comp Date:
Principal Investigator: John R. Claybaugh, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec; Clinical Investigation/Physiology		Associate Investigators: CPT Elizabeth Stafford, MC CDR J. Eduardo Fajardo, MC, USN
Key Words; Vasopressin Neonate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3,000.	Periodic Review Results; Completed

OBJECTIVE: To establish normal values of urinary vasopressin in the newborn, and determine if there is similar renal metabolism in infants as in adults. If not, when does it begin to occur?

TECHNICAL APPROACH: Urine was collected by free flow, by bag, or by wringing a diaper if newborn recently urinated. The urine was analyzed for osmolality, and creatinine concentration, and for vasopressin (VP) concentration by radioimmunoassay (RIA) with two antisera. The two antisera vary in their ability to detect a non-vasopressin substance which may be a metabolite of the hormone.

PROGRESS: We investigated the VP excretion in 62 children, ages one day to nine years to determine if the differential AS effect seen in RIA develops with age. Neither AS is significantly affected by the urea concentrations in urine; unextracted samples of urine were assayed for vasopressin. The "tail"-directed AS detected 192 ± 32 , 146 ± 25 , and 64 ± 8 μ U VP/mg creatinine at ages 1-5 days, 1-8 weeks, and 9-25 weeks, respectively. Comparable values for the "ring" AS were 208 ± 43 (NS), 195 ± 19 ($P < 0.05$), and 142 ± 17 ($P < 0.001$). After 9-25 weeks of age, this ratio of 64/142 (for the 2 AS) and the absolute values of VP were unchanged. Urine osmolality (Uosm) increased beginning at seven months of age. The results are compatible with the development of a VP metabolic process in the neonate that is completed by 6 months. The increasing Uosm during normal hydration begins after this time, but VP excretion remains unchanged. The increased Uosm during normal hydration begins after this time, but VP excretion remains unchanged. The increased Uosm is therefore not due to increased VP, but probably development of the urea gradient in the renal medulla.

Detail Summary Sheet

Date: 5 Jan 84	Prot No: 44/83	Status: Ongoing
TITLE: Specificity of Renal Tubular Mechanisms in the Metabolism of Vasopressin		
Start Date: Sep 83	Est Comp Date: Sep 85	
Principal Investigator: John R. Claybaugh, Ph.D.	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: Jill L. Sondeen, Ph.D. Catherine Uyehara, Grad Student Aileen K. Sato, Med Technol COL Samuel A. Cucinell, MC	
Key Words: Vasopressin; metabolism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$400.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: Immunologically detectable vasopressin activity in urine can be fractionated by high performance liquid chromatography (HPLC) into two major peaks. One peak corresponds to vasopressin. The other may be a metabolite of vasopressin. The objective of this research is to provide evidence that will either confirm or disprove the hypothesis that this non-vasopressin peak is a metabolite.

TECHNICAL APPROACH: If this non-vasopressin peak is the result of specific vasopressin enzymes that produce a metabolite of vasopressin, the enzyme system(s) should demonstrate saturability. For instance, as plasma concentrations of vasopressin increase, the non-vasopressin substance should increase to a point and then show a great reduction in the rate of increase. Also, analogues of vasopressin should be able to competitively inhibit the production of the non-vasopressin substance(s). These principals will be applied in human studies in which DDAVP, an antidiuretic synthetic analogue of vasopressin, will be administered and the renal clearance of vasopressin will be determined ($C_{AVP} = \frac{U_{AVP}}{P_{AVP}}$).

Also, the quantity of non-vasopressin substance will be measured after HPLC separation. If the non-vasopressin substance is produced by a specific enzyme system, DDAVP should decrease its production. In other studies, we will inject 3H -vasopressin into rats and collect urine. In this situation, two peaks of radioactivity can be detected after HPLC analysis of the urine. Competitive inhibition of this non-vasopressin peak will also be studied by injection of unlabeled vasopressin and analogues of vasopressin.

PROGRESS: We have demonstrated that 3H -vasopressin does appear in two fractions in the urine after HPLC analysis. These results will be published as part of a symposium publication listed in the summary of protocol No. 25/80. These radioactive peaks closely correspond to the immunologically detectable peaks of vasopressin activity. None of the other studies have been started at this time due to other priorities.

Detail Summary Sheet

Date: 26 Nov 84 Prot No: 29H/84 Status: Ongoing

TITLE: The Effects of 31 ATA on Circadian Patterns in Renal and Cardio-vascular Function

Start Date: Oct 84		Est Comp Date: Jan 85
Principal Investigator: John R. Claybaugh, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology		Associate Investigators:
Key Words: Saturation diving; hyperbaria; urine composition; vasopressin; renin, aldosterone; tilt table; circadian rhythms; cardiovascular responses		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in September 85

OBJECTIVE: An attempt will be made to determine the mechanism whereby saturation divers at 31 ATA (1000 ft sea water) experience a nocturnal diuresis.

TECHNICAL APPROACH: The study will be conducted at the Japan Marine Science and Technology Center (JAMSTEC). The four subjects will be male professional divers who work at JAMSTEC and have previously participated in saturation diving. The study will be conducted over a 30-day period from 28 September to 29 October 1984. There will be sea level values taken on days 1-5. Compression will be extended over days 6 and 7, constant 31 ATA pressure on days 8-13, decompression from day 14 to day 25, and a postdive control period from day 26 to day 30.

PROGRESS: Protocol approved in September 1984.

Detail Summary Sheet

Date: 7 Nov 84 Prot No: 3/82 Status: Terminated

TITLE: Childbirth Outcomes and Postpartum Psychological Reactions as a Function of Maternal Ability to Relax and Childbirth Preparation

Start Date: Feb 84		Est Comp Date:
Principal Investigator: CPT Wayne R. Coussens, MSC		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation		Associate Investigators:
Key Words: Postpartum psychological reactions Childbirth preparation Relaxation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To assess (1) effects of mothers' ability to relax and psychoprophylactic preparation on labor outcomes and loss of emotional control, and (2) postpartum psychological effects of losing control during labor.

TECHNICAL APPROACH: 200 uncomplicated pregnant females will be assessed for ability to relax at 28 and 38 weeks' gestation. They will complete a variety of psychological tests and questionnaires prior to labor and postpartum, designed to assess present emotional status and changes in that status. Intercorrelations will be made among test variables, relaxation ability, preparation for labor, and labor outcome measure taken from medical records.

PROGRESS: Due to the loss of co-investigator and the unavailability of adequate personnel support for this extensive project, data collection has not yet begun. Since the project requires approximately 18 months to complete and the principal investigator will be rotating within the next 8 months, this project cannot be completed. It is therefore terminated.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: NSABP B12(84)		Status: Ongoing
TITLE: A Protocol to Compare Melphalan-5-FU-Tamoxifen With and Without Adriamycin in the Management of Patients With Primary Breast Cancer and Positive Axillary Nodes Whose Tumors are Positive for Estrogen Receptors				
Start Date: Jan 84		Est Comp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC		
Key Words: Breast cancer				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue		

OBJECTIVE: To determine if adding Adriamycin to 3 other drugs will decrease the chances of breast cancer recurring after the primary surgery.

TECHNICAL APPROACH: All patients are randomized to receive one of 2 treatment programs: (1) Melphalan plus 5-FU plus tamoxifen every 6 weeks for 2 years or melphalan plus 5-FU plus adriamycin plus tamoxifen for the same period.

PROGRESS: One Tripler patient has been registered on this protocol. Nationally, this protocol has accrued a very large number of patients and will close soon.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: NSABP B11(84)		Status: Ongoing
TITLE: A Protocol to Compare Melphalan-5-FU With and Without Adriamycin in the Management of Patients With Primary Breast Cancer and Positive Axillary Nodes Whose Tumors Are Negative for Estrogen Receptors				
Start Date: Jan 84		Est Comp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC		
Key Words: Breast Cancer				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue		

OBJECTIVE: To determine if adding Adriamycin to 2 other drugs will decrease the chances of breast cancer recurring after primary surgery.

TECHNICAL APPROACH: All patients registered on this protocol are randomized to receive either (1) melphalan plus 5-FU every 6 weeks for 2 years or (2) melphalan plus 5-FU plus Adriamycin for the same time period.

PROGRESS: One Triper patient has been registered on this protocol. Nationally this protocol has accrued a very large number of patients and will be closing soon.

Detail Summary Sheet

Date: 29 Nov 84	Prot No: 15H/84	Status: Terminated
TITLE: Creatine Phosphokinase in Exercising Men		
Start Date: Feb 84	Est Comp Date:	
Principal Investigator: CPT Paul Davis, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Family Practice	Associate Investigators: COL Samuel A. Cucinell, MC LTC Robert Hill, MC Charles Wade, Ph.D.	
Key Words: Creatine phosphokinase		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To show if the elevated creatine phosphokinase which is markedly elevated in some black recruits post-exercise is present in all black men and to show the kinetics of this biochemistry.

PROGRESS: This project is terminated. It is being resubmitted as a new protocol.

Detail Summary Sheet

Date: 21 Dec 84 Prot No: 17A/84 Status: Ongoing
 TITLE: The Hormonal Control of Amniotic Fluid Volume

Start Date: Apr 84		Est Comp Date: Apr 86
Principal Investigator: Catherine F.T. Uyehara		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology		Associate Investigators: John R. Claybaugh, Ph.D.
Key Words: Amniotic fluid Vasopressin Vasotocin Omolality		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3,000.	Periodic Review Results: To be reviewed in Apr 85

OBJECTIVE: To assess the endocrine regulation of amniotic fluid (AF) volume and composition during the second and third trimesters of gestation. We wish to (1) document the levels of vasopressin (ADH), prolactin (PRL), cortisol (CORT), and aldosterone (ALDO) throughout gestation; (2) determine whether there is a correlation between AF osmolality and ADH/PRL/CORT/ALDO concentration; and (3) determine whether there is a correlation between AF volume and ADH/PRL/CORT/ALDO levels.

PROGRESS: Thus far, amniotic fluid from 19 fetuses of gestational ages 37-72 days (from nine mothers) has been successfully obtained for baseline values. Amniotic fluid from 7 fetuses of three untimed pregnancies has also been sampled. Osmolality and Na/K of all samples have been measured. Preliminary results show that osmolality decreases as gestational age increases from the 2nd trimester to term (contrary to human studies where amniotic fluid osmolality increases with increasing age). Levels of Na+ decrease and K+ levels increase with age. ADH, ALDO, and CORT levels are presently being analyzed. Baseline samples will continue to be gathered. Recovery of the pregnant animals from Ketamine/rompun anesthesia was poor with six out of seven animals dying before four days postsurgery. Halothane anesthesia enables more complete and immediate recovery and so will be used for the amniocentesis procedure from now on. Presently, the ability of the guinea pig to recover from surgical stress is being examined.

Detail Summary Sheet

Date: 7 Nov 84 Prot No: 22A/84 Status: Ongoing

TITLE: Effect of Cortisol on the Renal Handling of Vasopressin Using the Stop-Flow Technique in Pigs

Start Date: Jan 84		Est Comp Date: Nov 85
Principal Investigator: Jill L. Sondeen, Ph.D.		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Physiology		Associate Investigators: John R. Claybaugh, Ph.D. Aileen K. Sato CPT William S. Stokes, VC
Key Words: Vasopressin Stop-flow technique		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1200.	Periodic Review Results: To be reviewed in Jan 85

OBJECTIVE: To determine whether cortisol can alter the renal handling of vasopressin.

TECHNICAL APPROACH: The stop-flow technique is being used in pigs to assess how and where along the nephron, cortisol and/or aldosterone may be affecting the handling of vasopressin. An adrenalectomy is performed so that the plasma levels of cortisol and aldosterone can be experimentally controlled. One stop-flow procedure is performed under control conditions. The corticosteroid is infused for 90 minutes and then another stop-flow procedure is performed. In an anesthetized pig, one kidney is exposed and the ureter is catheterized. A rapid diuresis is induced by infusing the pig with mannitol. The ureteral catheter is clamped for 8 minutes and urine flow into the kidney ceases almost immediately because of the rapid increase in back pressure of the urine. During the 8 minutes of stopped flow, each specific tubular segment of the nephron acts maximally on its tubular fluid. The clamp is then released and the whole column of tubular fluid is pushed out almost intact. The urine is collected in 1 ml fractions; the initial fractions represent the most distal segments of the nephron, and the last fractions collected represent the proximal tubule and new filtrate. Specific substances are infused into the pig and can be used as markers of the specific tubular segments and functions.

PROGRESS: Three pigs have been studied with cortisol and two pigs have been studied with aldosterone. Four pigs did not have complete experiments run because of technical difficulties. One more aldosterone pig and three time-control pigs will be run. The data are still being analyzed and no conclusions have been made.

Detail Summary Sheet

Date: 7 Nov 84	Prot No: 33/83	Status: Ongoing
TITLE: Site and Mechanism of Formation of the Urinary Metabolite of Vasopressin in the Pig Using the Stop-Flow Technique		
Start Date: Jul 83	Est Comp Date: Jun 85	
Principal Investigator: Jill L. Sondeen, Ph.D.	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: John R. Claybaugh, Ph.D. Aileen K. Sato CPT William S. Stokes, VC	
Key Words: Vasopressin; metabolism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1500.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine where in the nephron the metabolite of vasopressin appears and by what mechanism.

TECHNICAL APPROACH: The stop-flow technique is being used in pigs to assess how and where along the nephron a metabolite of vasopressin is formed. In an anesthetized pig, one kidney is exposed and the ureter is catheterized. A rapid diuresis is induced by infusing the pig with mannitol. The ureteral catheter is clamped for 8 minutes and urine flow into the kidney ceases almost immediately because of the rapid increase in back pressure of the urine. During the 8 minutes of stopped flow, each specific tubular segment of the nephron acts maximally on its tubular fluid. The clamp is then released and the whole column of tubular fluid is pushed out almost intact. The urine is collected in 1 ml fractions; the initial fractions represent the most distal segments of the nephron, and the last fractions collected represent the proximal tubule and new filtrate. Specific substances are infused into the pig and can be used as markers of the specific tubular segments and functions. Creatinine is used as a marker for new filtrate; para-amino hippuric acid is used as a marker for the proximal tubule; sodium and potassium concentrations are used as markers for the distal tubule. Inulin is used as a marker for the extent of water reabsorption. By comparing whether the concentration of a substance is greater or less than the concentration of inulin, one can determine whether the substance was secreted or reabsorbed by the nephron.

PROGRESS: Six pigs have been studied. The results showed that vasopressin is reabsorbed and/or degraded in the proximal tubule. There appears to be no secretion of vasopressin into the distal tubule.

The results were presented at The Vasopressin Conference at Aspen, Colorado on August 29, 1984.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 12A/84	Status: Ongoing
TITLE: Relationship of the Immune Response to the Heat Sensitivity of the Moloney Virus-Induced YAC Lymphoma in Mice		
Start Date: Jan 84	Est Comp Date: Jan 86	
Principal Investigator: MAJ Michael Lieberman, MSC	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Microbiology	Associate Investigators: Arnold Feldman Ph.D. MAJ William J. Uphouse, MC COL Jeffrey Berenberg	
Key Words: Immunity to heat-sensitive tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Jan 85

OBJECTIVE: To determine the nature of any humoral and/or cellular immune responses to heated Moloney virus (murine leukemia virus)-induced YAC (MULv-YAC) lymphoma cells.

TECHNICAL APPROACH: Viable (non-heated) YAC lymphoma cells are highly tumorigenic and cause death in animals inoculated with these cells. The experiments to be performed are designed to answer the following questions: (a) Can the administration of heated (44°C, 25 min) tumor cells to mice "immunize" the animals against subsequent administration of non-heated cells ("active immunity")? (b) Can serum taken from mice given heated tumor cells transfer protection to mice that have not received heated cells, but subsequently are given non-heated cells ("passive immunity")? (c) Can spleen cells taken from mice given heated tumor cells transfer protection to mice that have not received heated cells, but subsequently are given non-heated cells ("adoptive immunity")?

PROGRESS: This protocol has not been initiated due to lack of sufficient support available, primarily for the care and maintenance of the animals (caging equipment and caretaker support).

Detail Summary Sheet

Date: 29 Oct 84 Prot No: 5A/84 Status: Ongoing
 TITLE: Cellular Immunity Against P. aeruginosa Derived from Immunization of Mice with a Pseudomonas Ribosomal Vaccine

Start Date: Dec 83		Est Comp Date: Dec 85
Principal Investigator: MAJ Michael M. Lieberman, MSC		Facility: Tripler Army Medical Center
Dept/Sec: Clinical Investigation/Microbiology		Associate Investigators:
Key Words: Cellular immunity; <u>P. aeruginosa</u> ; ribosomal vaccine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2,800	Periodic Review Results: Aug 84/Continue

OBJECTIVE: (1) To determine whether the immune response to the Pseudomonas ribosomal vaccine includes cellular elements capable of protection upon transfer to nonimmune animals (adoptive immunity).
 (2) To determine whether vaccinated mice rendered leukopenic are still protected against infection.

TECHNICAL APPROACH: A. Adoptive Immunity: Mice are immunized with the vaccine (20 per group). Spleens are excised from immunized mice and spleen cell suspensions prepared. (Spleen cell suspensions are also prepared from saline-administered mice.) Graded doses of immune and control spleen cells (from saline-administered mice) are injected (I.P.) into nonimmune mice (10 per group). Three days after injection of spleen cells, the mice are challenged with live cultures of P. aeruginosa. Challenged mice are scored for survival. Groups of mice receiving immune or control cells are compared. B. Challenge of immune leukopenic mice: Mice are immunized with the vaccine (10 per group). Cyclophosphamide is administered to both immune and control mice, again 3 days and 1 day prior to challenge. (Peripheral blood leukocyte counts will be made.) Mice are then challenged with live culture of P. aeruginosa. Challenged mice are scored for survival, comparing immune and control leukopenic mice. In addition, mice that were immunized but not rendered leukopenic, as well as nonimmune (control), nonleukogenic mice will be challenged as above. Thus, the efficacy of the vaccine in nonleukopenic mice will be compared to that in leukopenic mice.

PROGRESS: To date, 900 mice have been studied. A. Adoptive immunity experiments have shown a limited degree of cellular immunity. While statistically significant in some cases, the degree of protection achieved is not nearly as great as previously found for humoral immunity. B. The results obtained with leukopenic mice demonstrated that the vaccine is even more protective in leukopenic mice than in nonleukopenic mice. This result again indicates the importance of humoral immunity because the humoral function is highlighted as the cellular functions are depressed in leukemia.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 38/83	Status: Ongoing
TITLE: The Use of Monoclonal Antibody to a <u>Pseudomonas</u> Ribosomal Protein Antigen for Passive Immunization Against <u>P. aeruginosa</u>		
Start Date: Oct 83	Est Comp Date: Oct 86	
Principal Investigator: MAJ Michael M. Lieberman, MSC	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Microbiology	Associate Investigators:	
Key Words: Monoclonal antibody; <u>P. aeruginosa</u>		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$5,000.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa.

TECHNICAL APPROACH: Monoclonal antibodies are prepared by mixing spleen cells and myeloma cells in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, termed "hybridomas" since they are a hybrid of two different cells, have the myeloma cell properties of indefinite replication and of synthesizing only one particular immunoglobulin, but the immunoglobulin they synthesize is the antibody produced by the particular spleen cell that was fused. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens, and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of Pseudomonas ribosomal vaccines and passive mouse protection experiments will be performed.

PROGRESS: Hybridomas were produced by fusion of a non-secreting BALB/C murine myeloma cell line with BALB/C immune spleen cells, immunized either in vivo or in vitro with P. aeruginosa ribosomes or outer membrane preparation containing lipopolysaccharide (LPS). Hybridomas secreting antibodies reactive with either ribosomes or outer membranes were cloned and the monoclonal antibodies produced were characterized for antigenic specificity and isotype. Antibodies of three different specificities were found: (1) reactive with purified ribosomes but not with purified LPS, (2) reactive with purified LPS but not with ribosomes, and (3) reactive only with outer membranes. Results of isotyping showed that most antibodies were of the γ_1 or γ_2b heavy chain and λ light chain subclasses. These antibodies are currently being tested by an in vitro functional assay, as well as for passive mouse protection.

Ayala E, Lieberman M: Monoclonal Antibodies to a Ribosomal Vaccine from P. aeruginosa. Abstracts of the Annual Meeting of the American Society for Microbiology, St. Louis, March 1984, p. 69.

Detail Summary Sheet

Date: 7 Nov 84	Prot No: 33/83	Status: Ongoing
TITLE: Site and Mechanism of Formation of the Urinary Metabolite of Vasopressin in the Pig Using the Stop-Flow Technique		
Start Date: Jul 83	Est Comp Date: Jun 85	
Principal Investigator: Jill L. Sondeen, Ph.D.	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Physiology	Associate Investigators: John R. Claybaugh, Ph.D. Aileen K. Sato CPT William S. Stokes, VC	
Key Words: Vasopressin; metabolism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1500.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine where in the nephron the metabolite of vasopressin appears and by what mechanism.

TECHNICAL APPROACH: The stop-flow technique is being used in pigs to assess how and where along the nephron a metabolite of vasopressin is formed. In an anesthetized pig, one kidney is exposed and the ureter is catheterized. A rapid diuresis is induced by infusing the pig with mannitol. The ureteral catheter is clamped for 8 minutes and urine flow into the kidney ceases almost immediately because of the rapid increase in back pressure of the urine. During the 8 minutes of stopped flow, each specific tubular segment of the nephron acts maximally on its tubular fluid. The clamp is then released and the whole column of tubular fluid is pushed out almost intact. The urine is collected in 1 ml fractions; the initial fractions represent the most distal segments of the nephron, and the last fractions collected represent the proximal tubule and new filtrate. Specific substances are infused into the pig and can be used as markers of the specific tubular segments and functions. Creatinine is used as a marker for new filtrate; para-amino hippuric acid is used as a marker for the proximal tubule; sodium and potassium concentrations are used as markers for the distal tubule. Inulin is used as a marker for the extent of water reabsorption. By comparing whether the concentration of a substance is greater or less than the concentration of inulin, one can determine whether the substance was secreted or reabsorbed by the nephron.

PROGRESS: Six pigs have been studied. The results showed that vasopressin is reabsorbed and/or degraded in the proximal tubule. There appears to be no secretion of vasopressin into the distal tubule.

The results were presented at The Vasopressin Conference at Aspen, Colorado on August 29, 1984.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 38/83	Status: Ongoing
TITLE: The Use of Monoclonal Antibody to a <u>Pseudomonas</u> Ribosomal Protein Antigen for Passive Immunization Against <u>P. aeruginosa</u>		
Start Date: Oct 83	Est Comp Date: Oct 86	
Principal Investigator: MAJ Michael M. Lieberman, MSC	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation/Microbiology	Associate Investigators:	
Key Words: Monoclonal antibody; <u>P. aeruginosa</u>		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$5,000.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa.

TECHNICAL APPROACH: Monoclonal antibodies are prepared by mixing spleen cells and myeloma cells in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, termed "hybridomas" since they are a hybrid of two different cells, have the myeloma cell properties of indefinite replication and of synthesizing only one particular immunoglobulin, but the immunoglobulin they synthesize is the antibody produced by the particular spleen cell that was fused. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens, and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of Pseudomonas ribosomal vaccines and passive mouse protection experiments will be performed.

PROGRESS: Hybridomas were produced by fusion of a non-secreting BALB/C murine myeloma cell line with BALB/C immune spleen cells, immunized either in vivo or in vitro with P. aeruginosa ribosomes or outer membrane preparation containing lipopolysaccharide (LPS). Hybridomas secreting antibodies reactive with either ribosomes or outer membranes were cloned and the monoclonal antibodies produced were characterized for antigenic specificity and isotype. Antibodies of three different specificities were found: (1) reactive with purified ribosomes but not with purified LPS, (2) reactive with purified LPS but not with ribosomes, and (3) reactive only with outer membranes. Results of isotyping showed that most antibodies were of the γ_1 or γ_2b heavy chain and λ light chain subclasses. These antibodies are currently being tested by an in vitro functional assay, as well as for passive mouse protection.

Ayala E, Lieberman M: Monoclonal Antibodies to a Ribosomal Vaccine from P. aeruginosa. Abstracts of the Annual Meeting of the American Society for Microbiology, St. Louis, March 1984, p. 69.

Detail Summary Sheet

Date: 29 Nov 83		Prot No: 39/83	Status: Terminated
TITLE: Creative Phosphokinase (CPK) Response to Exercise in Glucose 6-Phosphate Dehydrogenase (G6PD) Type A ⁻ Men			
Start Date: Sep 83		Est Comp Date:	
Principal Investigator: COL Samuel A. Cucinell		Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation		Associate Investigators:	
Key Words: Glucose 6-phosphate dehydrogenase CPK			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated	

OBJECTIVE: To determine if glucose 6 PO₄ dehydrogenase is related to CPK increases in exercise.

TECHNICAL APPROACH: During the course of project #26/82 (Effect of Seven Consecutive Days of 2-hr Sessions of Strenuous Exercise on the Salt and Water Balance and Associated Hormonal Control Mechanism) it was determined that one man with glucose 6-phosphate dehydrogenase type A⁻ had marked elevations of CPK during exercise. We wish to determine if this is true for all individuals with this enzyme. A Bruce treadmill test will be used with samples taken at zero time, 30 minutes, 8 hours, and 24 hours. Six men with type A⁻ will be test subjects, and six black men with type A⁺ and six white men with type A⁺ will be controls.

PROGRESS: A review of the literature has shown that glucose 6 PO₄ dehydrogenase is not related to the marked increase in CPK in exercising black men and this study has been replaced by protocol number 15H/84.

Detail Summary Sheet

Date: 21 Dec 84		Prot No: 26/79		Status: Ongoing	
TITLE: Determination of Liver Blood Flow and Improved Technique for Sampling Hepatic Vein Blood					
Start Date: Jul 79			Est Comp Date:		
Principal Investigator: COL Samuel A. Cucinell, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Clinical Investigation			Associate Investigators: Gordon H. Bryant		
Key Words: Liver blood flow					
Accumulative MEDCASE Cost: \$23,000.		Est Accumulative OMA Cost: \$4,500.		Periodic Review Results: May 84/Continue	

OBJECTIVE: The establishment of a method of determining liver blood flow.

TECHNICAL APPROACH: The difference between the blood flow in the inferior vena cava above and below the hepatic veins is a measure of the liver blood flow. A noninvasive thermodilution technique for this determination using a thermistor placed percutaneously above and below the hepatic veins was developed. This technique was described for the laparotomized dog with both thermistors and electromagnetic flow probes placed in the indicated positions with good results (Western Pharmacol Soc 24:23-25, 1981). However, when this technique was applied to the pig without exposing the inferior vena cava, the results were erratic. The problems lie in the loss of thermal indicator as it progresses up the inferior vena cava.

PROGRESS: Only four pigs have been studied this year. Two large pigs gave excellent correlation of thermodilution measurement with electromagnetic flow probes, but two small pigs did not. Possibly the 13 cm fixed distance between thermistors is too great for smaller animals.

Bryant GH, Cucinell SA, Barcia PJ: Determination of Heat Gain in the Inferior Vena Cava During Thermodilution Measurements. Journal of Surgical Research (in press).

Detail Summary Sheet

Date; 7 Nov 84	Prot No: 21H/84	Status: Ongoing
TITLE: Effects of Altitude and Oxygen Supplementation on High Level Cognitive Performance and Psychomotor Skills		
Start Date: Jun 84	Est Comp Date: Sep 86	
Principal Investigator: CPT Wayne R. Coussens	Facility: Tripler Army Medical Center	
Dept/Sec: Clinical Investigation	Associate Investigators: Alvah C. Bittner, Jr., Ph.D. David D. Cudaback, Ph.D. Charles S. Houston, M.D. LT CDR Steve Tolan, Ph.D., USN	
Key Words: Altitude Cognitive performance Psychological performance		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Jun 85

OBJECTIVE: To assess the effects of altitude, pressure, oxygen depletion, and oxygen supplementation on performance of high level cognitive and psychomotor skills in people of various levels of intelligence,

TECHNICAL APPROACH: The study will be conducted in three phases. In the first phase, selection of appropriate tests sensitive to changes in pressure and oxygen will be made. In the second, the high altitude chamber will be used to examine the effects on cognitive performance of oxygen depletion and supplementation, along with pressure changes. The third phase consists of a high altitude field study in which "real life" problems and effects can be assessed. In each study, subjects will be blinded to conditions and will be tested using alternate forms of the same tests in repeated measures type design. Physiological and medical monitoring, video taped observational studies, motivational analyses will be used throughout the three phases both as data and as a means of assuring the safety and health of subjects.

PROGRESS: Data collection on this protocol has not yet begun. The protocol has been submitted to the U.S. Army Medical Research and Development Command for funding. Dependent upon approval of funding, it is projected that data collection can begin as early as March 1985.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: NSABP B13(84)		Status: Ongoing	
TITLE: A Protocol to Assess Sequential Methotrexate-5-FU in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Negative for Estrogen Receptor					
Start Date: Jan 84			Est Comp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology			Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC		
Key Words: Breast cancer					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: Nov 84/Continue	

OBJECTIVE: To determine if giving a relatively nontoxic chemotherapy program to women after surgery will decrease the chances of relapse and improve survival.

TECHNICAL APPROACH: All eligible patients are randomized to receive (1) chemotherapy with 5-FU and methotrexate twice a month for 1 year or (2) no treatment.

PROGRESS: A total of three Tripler patients have been registered on this protocol. No results are available yet, but the number of patients accrued nationally has been good.

Detail Summary Sheet

Date: 29 Nov 84		Prot No: NSABP B14(84)		Status: Ongoing
TITLE: A Protocol to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors.				
Start Date: Jan 84		Est Comp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC		
Key Words: Breast cancer				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue		

OBJECTIVE: To determine if Tamoxifen given to women after surgery for breast cancer will prolong survival and prevent recurrences.

TECHNICAL APPROACH: All patients who are eligible are randomized to (1) tamoxifen p.o. for 4 years or (2) placebo p.o. for 4 years.

PROGRESS: Three patients have been entered on this study from Tripler. No results are available yet, but accrual of patients has been excellent nationally.

Detail Summary Sheet

Date: 26 Nov 84		Prot No: NSABP B15(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Short Intensive Chemotherapy With or Without Reinduction Chemotherapy to Conventional CMF in Receptor-Negative Positive-Node Breast Cancer Patients			
Start Date: Sep 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Oncology-Hematology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC	
Key Words: Breast cancer			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Sep 85	

OBJECTIVE: To determine if a short course of chemotherapy in the adjuvant setting is as effective as the "standard" six months of CMF. Also, to determine if a later "reinduction" will improve survival.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to one of three treatment groups: (1) Adriamycin and Cytoxan for four cycles, (2) Adriamycin and Cytoxan as above, then, after six months of rest, three cycles of CMF, or (3) six cycles of CMF ("standard" therapy).

PROGRESS: Protocol approved in September 1984.

Detail Summary Sheet

Date: 26 Nov 84		Prot No: NSABP B16(84)		Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Tamoxifen Alone Versus L-PAM, 5-FU, and Tamoxifen Versus Short Intensive Adriamycin-Cyclophosphamide Plus Tamoxifen in Receptor-Positive Node-Positive Breast Cancer Patients				
Start Date: Oct 84		Est Comp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Oncology-Hematology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC		
Key Words: Breast cancer				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Sep 85		

OBJECTIVE: To determine if chemotherapy added to tamoxifen is superior to tamoxifen alone in the adjuvant therapy of receptor-positive breast cancer. Also, to determine which of two chemotherapy regimens, when added to tamoxifen, results in the best survival.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to one of three treatments: (1) tamoxifen alone for four years, (2) tamoxifen for four years, plus four cycles of Adriamycin and Cytosan, or (3) tamoxifen for four years, plus L-PAM and 5-FU every six weeks for 17 courses.

PROGRESS: Protocol approved in September 1984.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: NSABP C02(84) Status: Ongoing	
TITLE: A Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-FU and Heparin in Patients with Resectable Adenocarcinoma of the Colon			
Start Date: May 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: William Uphouse, MC Dominic Solimando, MSC COL Peter J. Barcia, MC	
Key Words: Colon adenocarcinoma			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in May 85	

OBJECTIVE: To determine if 5-FU infused through the portal vein for one week postoperatively will decrease the recurrence rate of operable adenocarcinoma of the colon in comparison to a control group given no therapy.

TECHNICAL APPROACH: Patients who appear to have Dukes A, B, or C colon cancer and who agree to participate will be randomized preoperatively to receive a 5-FU and heparin infusion via the portal vein for 7 days postoperatively or to receive no further therapy.

PROGRESS: Two Tripler patients have been entered to date. It is too early for any results as this protocol just opened.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 7804(84) Status: Ongoing	
TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III			
Start Date: Mar 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC COL Peter J. Barcia, MC	
Key Words: Gastric adenocarcinoma			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85	

OBJECTIVE: To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

TECHNICAL APPROACH: Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year for (2) receive no treatment.

PROGRESS: One Tripler patient was entered on this protocol. Nationally, 122 patients have been entered, and although disease-free survival is slightly better in the treated areas, the difference is not statistically significant.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 7808(83)		Status: Ongoing
TITLE: Combined Modality Treatment for Stage III and IV Hodgkin's Disease - MOPP 6, Phase III				
Start Date: Jul 83		Est Corp Date: Indefinite		
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William J. Uphouse, MC CPT Dominic Solimando, MSC MAJ Marylin P. Ordonez, MC MAJ Aida Ronquillo, MC		
Key Words: Hodgkin's disease				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue		

OBJECTIVE: To determine if radiation therapy given after the chemotherapy will increase the chance of being cured, and to see if a drug called levamisole given as a pill will increase the chance of being cured.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: National total patient accrual is 358. Ten patients have been entered from Tripler. Results so far show no difference in survival between patients randomized to receive the involved field irradiation and those randomized to no further treatment. One TAMC patient is still on active therapy at the present time. The protocol remains open for new entries.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 7916(84) Status: Completed

TITLE: Evaluation of Gallium Nitrate in Metastatic Bladder Cancer, Phase II

Start Date: Mar 84		Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Bladder cancer, metastatic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To determine the activity of a new chemotherapy drug, gallium nitrate, in metastatic bladder cancer.

TECHNICAL APPROACH: All patients will receive gallium nitrate by vein once every 3 weeks until their disease progresses.

PROGRESS: One patient from Tripler has been entered on this study and had a partial remission (more than 50% tumor shrinkage) to the treatment. Of all patients entered on this study, only a very small number responded (nationally). There are no TAMC patients on treatment presently and it is closed to new entries. It is therefore considered completed.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 7990(84) Status: Ongoing

TITLE: Testicular Cancer Intergroup Study (TC 279)

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Testicular cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine if chemotherapy given over a 2-month period will decrease the relapse rate and improve survival in patients with testicular cancer which has spread to the retroperitoneum (but has been removed surgically).

TECHNICAL APPROACH: Patients with retroperitoneal involvement will be randomized to the two months of chemotherapy (after the surgery) or to no further treatment.

PROGRESS: Four Tripler patients have been entered on this study to date. Preliminary results show a much higher relapse rate and the only deaths so far were in the non-treated group.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8001(84) Status: Ongoing	
TITLE: Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III			
Start Date: Aug 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC	
Key Words: Leukemia, lymphoblastic			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85	

OBJECTIVE: To compare two maintenance chemotherapy regimens (LIO and POMP) in terms of response, duration, and survival.

TECHNICAL APPROACH: All patients agreeing to participate in this study will receive the same weekly induction and consolidation therapy with prednisone, vincristine, and Adriamycin, but will then be randomized to receive either the LIO or POMP regimens for maintenance (for 36 months).

PROGRESS: One Tripler patient has been entered on this study to date. The POMP arm has been closed as the LIO arm was superior. The protocol remains open for further accrual to accurately assess response rates and survival, both of which appear very good compared to prior studies.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8040/44 (84) Status: Terminated

TITLE: Evaluation of Combination Chemotherapy (FAM-S) Versus a Phase II Drug (AZQ) in Pancreatic Adenocarcinoma, Phase II

Start Date: Jan 84	Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Pancreatic adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: Terminated

OBJECTIVE: To compare two treatment programs for cancer of the pancreas that has spread beyond surgical resectability and a reasonable radiation port, i.e., metastatic.

TECHNICAL APPROACH: This protocol randomizes patients to receive (1) combination chemotherapy with FAM-S or (2) a new drug called AZQ.

PROGRESS: No Tripler patients were entered on this trial and it is now closed to new entries.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8049(84) Status: Ongoing

TITLE: The Treatment of Resected, Poor Prognosis Malignant Melanoma
Stage I: Surgical Excision Versus Surgical Excision + Vitamin A, Phase III

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Melanoma, malignant		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine if vitamin A given daily by mouth will decrease the relapse rate and improve survival in patients who have had poor prognosis melanomas completely resected.

TECHNICAL APPROACH: Patients with melanomas that extend deeper than .76 mm and that have been completely resected are randomized to receive vitamin A daily by mouth for 18 months or to receive no therapy.

PROGRESS: Seven Tripler patients have been entered on this study. There are no results available on this study yet, although 185 patients have been entered nationally to date.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8104(83) Status: Ongoing

TITLE: Treatment of Advanced Seminoma (Stage CII(N₄) + CIII) with Combined Chemotherapy and Radiation Therapy, Phase II

Start Date: Jul 83		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William J. Uphouse, MC CPT Dominic Solimando, MSC MAJ Marylin P. Ordonez, MC MAJ Aida Ronquillo, MC
Key Words: Seminoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue

OBJECTIVE: To determine if combined chemotherapy and radiation therapy is more effective in treatment of advanced seminoma than radiation therapy alone.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: Total patient accrual to date is 21. Two patients have been registered from TAMC to date. This protocol tests the value of chemotherapy given to patients with bulky seminoma prior to the usual radiation therapy. Of eight evaluable patients, five patients achieved complete remission and three achieved partial remission. Survival results are still pending.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8107(84) Status: Ongoing

TITLE: Management of Disseminated Melanoma Master Protocol

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Melanoma, disseminated		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine the relative activity of 3 chemotherapy programs in patients with metastatic melanoma: (1) DTIC and Actinomycin-D (2) Cis-platinum and (3) Cis-platinum, Velban, and Bleomycin. In addition, to determine if prophylactic cranial irradiation will prevent the later development of brain metastases.

TECHNICAL APPROACH: Patients with metastatic melanoma are randomized to receive or not to receive 5 days of prophylactic cranial radiation. They are also randomized to receive one of the three chemotherapy programs listed above.

PROGRESS: Six patients from Tripler have been entered. Results to date nationally do not show a clear advantage for any of the three arms over any other arm.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8305(84) Status: Ongoing

TITLE: Chemotherapy of Metastatic Colorectal Carcinoma With 5-FU and Folinic Acid, Phase II

Start Date: Jan 84	Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Colorectal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: Nov 84/Continue

OBJECTIVE: To determine the activity of a new chemotherapy program for metastatic colon or rectal cancer.

TECHNICAL APPROACH: All patients who are eligible are randomized to either a 4 or 5 day schedule of 5-FU plus folinic acid.

PROGRESS: One Tripler patient was entered on this study in 1984. Nationally, 128 patients were entered and the response rate was 25% overall. One Tripler patient remains on active chemotherapy at the present time.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8300(84) Status: Ongoing	
TITLE: Treatment of Limited Non-small Cell Lung Cancer: Radiation Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III			
Start Date: Aug 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC	
Key Words: Lung cancer, non-small cell			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85	

OBJECTIVE: To determine whether chemotherapy added on to standard radiation therapy in patients with limited, non-small cell lung cancer will improve response rates and survival.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive (1) definitive radiation therapy alone, or (2) 8 weeks of FOMi/CAP followed by definitive radiation and then two further cycles of FOMi/CAP. All patients are also randomized to receive or not receive prophylactic cranial irradiation.

PROGRESS: One Tripler patient was registered on this protocol in 1984. There is no data on this protocol as it was just approved in August.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8291/8391(84) Status: Ongoing
 TITLE: The Intergroup Adult Adjuvant Soft Tissue Sarcoma, Protocol #122

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Sarcoma, soft tissue		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine if Adriamycin given after either surgery or surgery plus irradiation will prolong survival and prevent relapses in patients with soft-tissue sarcomas with poor prognosis.

TECHNICAL APPROACH: Patients with poor prognosis soft-tissue sarcomas that have been completely resected (SWOG 8291) or that are either inoperable or incompletely resected (SWOG 8391) are randomized (after radiation therapy if indicated) to receive Adriamycin every 3 weeks for five doses or to receive no treatment.

PROGRESS: No Tripler patients have been entered on this study as yet.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8245(83) Status: Completed

TITLE: Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB (Alternating), Phase II

Start Date: Jul 83	Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William J. Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Lymphoma, non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: Completed

OBJECTIVE: To test the value of a new program of alternating combination chemotherapy in advanced lymphoma.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: Total patient accrual to date is 215. Two patients were registered from TAMC, but no TAMC patients remain on therapy at the present time. The protocol is closed to new entries and is therefore considered completed.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8241(84) Status: Ongoing	
TITLE: Treatment for Advanced Non-small Cell Lung Cancer: PV _p versus PV _M versus PV _C versus PV _C Mi versus FOMI/CAP, Phase III			
Start Date: Mar 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC	
Key Words: Lung cancer, non-small cell			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300	Periodic Review Results: To be reviewed in Mar 85	

OBJECTIVE: To determine the relative activity of five chemotherapy programs for the treatment of metastatic non-small (oat) cell lung cancer.

TECHNICAL APPROACH: Patients with non-small cell lung cancer that is metastatic are randomized to one of five programs of chemotherapy. Each program has been piloted with a small number of patients and appears promising.

PROGRESS: Three Tripler patients have been entered on this study to date. Nationally, 660 patients have been entered. It is still too early for meaningful comparisons between arms.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: SWOG 8232(84)	Status: Ongoing
TITLE: Treatment of Limited Small Cell Lung Cancer with VP16/Cis-Platinum, Alternating With Vincristine/Adriamycin-Cyclophosphamide and Radiation Therapy Versus Concurrent VP16/Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy, Phase III		
Start Date: Jan 84	Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC MAJ Marilyn Ordonez, MC	
Key Words: Lung cancer, small cell		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Nov 84/Continue

OBJECTIVE: To compare the effectiveness of two chemotherapy programs for the treatment of small cell lung cancer that is clinically limited to one hemithorax.

TECHNICAL APPROACH: All patients eligible will receive either the four-drug combination (EVAC) or a three-drug regimen: VAC (the three-drug regimen is alternated with two other drugs listed above).

PROGRESS: Three patients from Tripler have been entered on this study. Five hundred thirty-one patients have been entered nationally. Early results suggest possible superiority of the arm that alternates three and two drugs.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8217(84) Status: Ongoing

TITLE: Evaluation of Spirogermanium in Adenocarcinoma of the Prostate, Phase II

Start Date: Mar 84	Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Prostate adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine the activity of a new drug, Spirogermanium, in patients with metastatic prostate cancer who have failed prior hormonal therapy.

TECHNICAL APPROACH: All patients will receive the drug IV three times a week until their disease progresses.

PROGRESS: No Tripler patients have been registered on this protocol. Twenty-seven patients have been entered nationally. No results are yet available.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8211(83) Status: Completed

TITLE: Evaluation of CIS-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II

Start Date: Jul 83		Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William J. Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Gastric adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To test the value of CIS-platinum chemotherapy in advanced gastric carcinoma.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: Twenty-five patients nationally have been entered to date. Two patients from Tripler were entered on this protocol, 1 in 1983 and 1 in 1984, but no TAMC patients remain on treatment at the present time. This protocol is closed to new entries. The protocol is therefore considered completed. No data is available on results at this time.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8210(84) Status: Terminated

TITLE: A Comparison of Aggressive Radiotherapy Plus Chemotherapy Versus Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas, Phase III

Start Date: Jan 84	Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Pancreatic cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: Terminated

OBJECTIVE: To compare two treatment programs for patients who have unresectable cancer of the pancreas which has not yet spread beyond the area around the pancreas.

TECHNICAL APPROACH: Patients are randomized to either (1) combination chemotherapy (FAMS) twice a month until their disease progresses or (2) radiation to the pancreas and simultaneous 5-FU.

PROGRESS: No Tripler patients were entered on this protocol which has been closed to entry. Accrual on this protocol was poor nationally (24 patients total).

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8207(84) Status: Terminated

TITLE: Evaluation of AZQ in Advanced Renal Cell Carcinoma, Phase II

Start Date: Mar 84	Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology	Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Renal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: Terminated

OBJECTIVE: To determine the activity of a new drug, AZQ, in patients with metastatic renal cell carcinoma.

TECHNICAL APPROACH: All patients registered in this study will receive AZQ IV every 3 weeks until their disease progresses.

PROGRESS: No Tripler patients were registered on this protocol which is now closed. Nationally, 58 patients were entered but very few responses were seen.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8203/04(84) Status: Terminated	
TITLE: Randomized Comparison of Adriamycin, Mitoxantrone and Bisantrone in Patients with Metastatic Breast Cancer Not Previously Exposed to Intercalating Chemotherapy, Phase III			
Start Date: Mar 84		Est Comp Date:	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC	
Key Words: Breast cancer, metastatic			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated	

OBJECTIVE: To determine the relative activity of three chemotherapy drugs in metastatic breast cancer.

TECHNICAL APPROACH: Patients who have failed first-line chemotherapy with non-Adriamycin drugs are randomized to receive one of the three drugs by vein once every 3 weeks.

PROGRESS: No Tripler patients have been entered on this trial and, as a result, the protocol was closed to Tripler patients. This is unfortunate as this is an important study.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8124/25/26(84) Status: Ongoing	
TITLE: Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy Versus Bone Marrow Transplantation, Phase III			
Start Date: Mar 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC	
Key Words: Leukemia, non-lymphocytic			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85	

OBJECTIVE: This study is twofold. First, it seeks to determine whether further chemotherapy or whether bone marrow transplantation is best for patients who achieve complete remission with initial chemotherapy. Second, it seeks to determine whether maintenance chemotherapy is superior to no maintenance chemotherapy in patients who successfully complete 3 months of initial chemotherapy.

TECHNICAL APPROACH: After the patient achieves complete remission, he or she is randomized to receive a bone marrow transplant (if the patient has an appropriate donor and agrees to this) or to receive consolidation chemotherapy. Patients who complete the 2 months of consolidation chemotherapy are then randomized to receive or not to receive maintenance chemotherapy.

PROGRESS: Two Tripler patients have been entered in this protocol. Nationally, 338 patients have been entered to date. There have been a number of early deaths in the group undergoing bone marrow transplants, but longer follow-up will be necessary to assess final outcome.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8122(84) Status: Ongoing
 TITLE: Combined Modality Treatment of Extensive Small Cell Lung Cancer,
 Phase III

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC MAJ Marilyn Ordonez, MC
Key Words: Lung cancer, small cell		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To compare two chemotherapy programs for the treatment of small cell lung cancer that has metastasized outside of the chest.

TECHNICAL APPROACH: The patients in this study are randomized to receive either the "standard" three drugs (CAV) or the new four-drug program (BTOC).

PROGRESS: Four patients have been entered to date from Tripler. Results to date show 251 eligible patients nationally and show inferiority to the BTOC arm which has been closed. Results published in ASCO 1984 (C-821).

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8111(84) Status: Completed

TITLE: The Treatment of Resected, Poor Prognosis Malignant Melanoma:
Stage II, Phase III

Start Date: Mar 84		Est Comp Date:
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Melanoma, malignant		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To determine if either of two treatment programs will prevent or delay relapses and prolong survival in patients with melanoma that has spread to lymph nodes and that has been completely resected. The two treatments are (1) vitamin A, and (2) actinomycin D and DTIC.

TECHNICAL APPROACH: Patients with positive lymph nodes that have been resected are randomized to one of three treatments: (1) vitamin A given orally daily for 12 months, (2) Actinomycin D and DTIC given IV once a month for 12 months, or (3) no treatment.

PROGRESS: One Tripler patient was registered in 1984, but no TAMC patients are being actively treated at the present time. The protocol is closed to new entries. The protocol is therefore considered completed. No data on results are available yet.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8308(84) Status: Ongoing	
TITLE: Combination Cis-platinum and Dichloromethotrexate in Patients with Advanced Bladder Cancer, Phase II			
Start Date: May 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC	
Key Words: Bladder cancer			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in May 85	

OBJECTIVE: To determine the response rate of metastatic bladder cancer to a new combination of two chemotherapy drugs, cis-platinum and dichloromethotrexate in patients with good renal function. This study will also look at the response rate of dichloromethotrexate alone in patients with impaired renal function.

TECHNICAL APPROACH: Patients with good renal function will receive two doses of cis-platinum IV one month apart, then one dose every six weeks. They will also receive dichloromethotrexate IV weekly times 8, then every two weeks. Patients with impaired renal function will receive only the dichloromethotrexate.

PROGRESS: No Tripler patients have been entered on this study as yet. Thirteen patients have been entered nationally.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8316(84) Status: Ongoing	
TITLE: Evaluation of Fludarabine Phosphate in Renal Cell Carcinoma, Phase II			
Start Date: Jun 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC	
Key Words: Renal cell carcinoma			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Jun 85	

OBJECTIVE: To determine the response rate of advanced renal cell carcinoma to a new chemotherapy drug, fludarabine.

TECHNICAL APPROACH: Fludarabine will be given to consenting patients as an IV bolus each day for 5 days every 4 weeks.

PROGRESS: No Tripler patients have been entered on this study as yet.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8318(84) Status: Ongoing

TITLE: Evaluation of Fludarabine Phosphate in Hepatoma, Phase II

Start Date: Aug 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC
Key Words: Hepatoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85

OBJECTIVE: To determine the response rate and response duration of hepatomas treated with a new drug, fludarabine.

TECHNICAL APPROACH: All patients agreeing to participate in this study will receive fludarabine IV bolus day 1 through day 5 every 28 days until their tumor progresses.

PROGRESS: No Tripler patients have been entered on this study as it was approved in August.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8386(84) Status: Completed	
TITLE: Evaluation of Fludarabine Phosphate in Colorectal Carcinoma, Phase II			
Start Date: May 84		Est Comp Date:	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC	
Key Words: Colorectal carcinoma			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed	

OBJECTIVE: To determine the response rate of metastatic colon or rectal cancer to a new drug, fludarabine.

TECHNICAL APPROACH: All patients wishing to participate will receive fludarabine IV day 1 through day 5 every 28 days. Two courses (2 months) of therapy will be considered an adequate trial for patients who do not respond to the drug.

PROGRESS: One patient from Tripler was entered with stabilization of his liver metastasis. No national data is available.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8390(84) Status: Ongoing

TITLE: Chemotherapy of Gastric Cancer with 5-FU and Folinic Acid, Phase II

Start Date: May 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC
Key Words: Gastric cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in May 85

OBJECTIVE: To determine the response rate of metastatic gastric carcinoma to a new combination of drugs (5-FU and folinic acid).

TECHNICAL APPROACH: Patients who agree to participate will be randomized to receive 5-FU either by constant IV infusion on day 1 through day 4, or by IV bolus on day 1 through day 5. Folinic acid will be given in both arms by IV bolus on each day of 5-FU. Courses will be repeated monthly.

PROGRESS: No Tripler patients have been entered on this study as yet.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: SWOG 8393(84) Status: Ongoing
 TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma

Start Date: May 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC CPT Dominic Solimando, MSC COL Peter J. Barcia, MC
Key Words: Melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in May 85

OBJECTIVE: (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

TECHNICAL APPROACH: Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

PROGRESS: No Tripler patients have been registered on this protocol as yet.

Detail Summary Sheet

Date: 27 Nov 84 Prot No: SWOG 8403(84) Status: Ongoing

TITLE: Evaluation of Fludarabine in Squamous Cell Carcinoma of the Head and Neck Region, Phase II

Start Date: Oct 84		Est Comp Date: Indefinite
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC
Key words: Squamous cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Sep 85

OBJECTIVE: To determine the response rate and response duration of advanced head and neck cancer to a new drug.

TECHNICAL APPROACH: All patients agreeing to participate will receive fludarabine as an IV infusion over 30 minutes on day 1 to 5 every 28 days until their disease progresses.

PROGRESS: Project approved in September 1984.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: SWOG 8410(84) Status: Ongoing	
TITLE: Combination Chemotherapy of Intermediate and High-Grade Non-Hodgkin's Lymphoma with m-BACOD, Phase II			
Start Date: Aug 84		Est Comp Date: Indefinite	
Principal Investigator: COL Jeffrey Berenberg, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: MAJ William Uphouse, MC MAJ Daniel Tell, MC COL Viola Brooks, MC CPT Dominic Solimando, MSC	
Key Words: Lymphoma, non-Hodgkin's			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85	

OBJECTIVE: To determine the response rate and duration of response to a new chemotherapy regimen for aggressive lymphomas.

TECHNICAL APPROACH: All patients who agree to participate will receive weekly chemotherapy with the six drugs being given intermittently for a total of 30 weeks.

PROGRESS: No Tripler patients have been entered on this study as it has just opened.

Detail Summary Sheet

Date: 30 Sep 84 Prot No: 24/83 Status: Ongoing

TITLE: Evolution of House Dust Mite Sensitivity and Home Colonization in Newly Arrived Military Personnel to Hawaii

Start Date: Apr 83	Est Comp Date: Jun 85
Principal Investigator: LTC Gary B. Carpenter, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Allergy	Associate Investigators: Douglas G. Massey, MD Doug Win, MS
Key Words: House dust mite; air conditioning	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3,000.
	Periodic Review Results: May 84/Continue

OBJECTIVE: To investigate the rate and extent of colonization of newly arrived military households with Dermatophagoides pteronyssinus (Dp) and the rate and extent of allergic sensitization to Dp in patients already allergic to D. farinae (Df) in these households in a controlled study. To assess the effect of central air conditioning on mite density and mite species in military households.

TECHNICAL APPROACH: This project was changed in order to include a controlled study of the effect of central air conditioning on mite populations and species in military homes. Skin testing to both Df and Dp was done on 100 patients to assess military sensitization to these two mite species.

PROGRESS: The original goal to assess house dust mite sensitivity in newly arrived military personnel to Hawaii had to be changed because of withdrawal of initial FDA approval of Center Dp and Df extracts for skin testing. Before withdrawal of approval, 100 patients were skin tested. The study of the effect of air conditioning on house dust mite density and species is nearly complete and clearly shows that air conditioning has major effects on these two parameters. This is of major importance to the management of patients with house dust mite allergy since air conditioning may be required for adequate control of their asthma and rhinitis. As of Apr 85, the sampling of the two homes over a one-year period will be completed. All mite isolation and identification should be completed by Jun 85. Because of the resources directed to the air-conditioning study, only one home will be studied addressing the question of home colonization of newly arrived military personnel. This home is being rigorously studied with sampling of five different sites in the home. Sampling should be completed by Mar 85 with all results in by Jun 85.

Detail Summary Sheet

Date: 23 Dec 83 Prot No: 40/83 Status: Ongoing

TITLE: Double-Blind Comparison of Alum-precipitated House Dust Mite Therapy in the Treatment of Allergic Asthma and Rhinitis

Start Date: Jan 83	Est Comp Date: Sep 86
Principal Investigator: MAJ Gary B. Carpenter, MC	Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Allergy	Associate Investigators: LTC Anna A. Ortiz, MC Douglas G. Massey, M.D.
Key Words: House dust mite	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$5,000.
	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To compare allergy immunotherapy with alum-precipitated extracts of Dermatophagoides pteronyssinus (Dp) and/or D. farinae (Df) in a double-blind placebo controlled study in patients with house dust mite allergy.

TECHNICAL APPROACH: Sixty patients with house dust mite allergy with significant rhinitis with or without asthma will be studied for a minimum of 6 months each. Once they volunteer, they will receive end point titration skin tests (either intradermal or prick) to D. farinae and D. pteronyssinus. They will be allocated to four groups by a double-blind stratified randomization procedure performed by the Pharmacy Service, TAMC. Patients will keep a symptom and medication score sheet of asthma and rhinitis symptoms and medications used for the week before their monthly visit to the clinic. All patients will have their mattresses and bedroom and living room floors sampled for house dust mite.

PROGRESS: This protocol is stalled due to failure of the FDA to approve the center alum-precipitated extract to be used for therapy and the aqueous extract to be used for skin testing. They had concerns that the media used for growing the house dust mites might cause sensitization. We recently completed RAST tests in nine patients highly allergic to house dust mite showing no significant sensitization to any of the media components. This data will be forwarded to the FDA, and hopefully, the approval will be forthcoming.

GIFTS: The material for the RAST tests was provided gratis by Center Laboratories, Inc.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: 3H/84 Status: Completed

TITLE: Renal Morphology in a Patient with Epidemic Hemorrhagic Fever:
Hemorrhagic Nephrosonephritis

Start Date: Dec 83		Est Comp Date:
Principal Investigator: MAJ L. Harrison Hassell, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Nephrology		Associate Investigators:
Key Words: Hemorrhagic nephrosonephritis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To evaluate renal morphology by light immunofluorescent and electron microscopy in a patient with Korean hemorrhagic fever with specific emphasis on immunofluorescent staining for the presence of the han taan viral antigen.

TECHNICAL APPROACH: The biopsy specimen was processed by existing SOPs within the Department of Pathology. Antisera to the han taan viral antigen was supplied by Dr. Kelly McKee at USAMRIID.

PROGRESS: This protocol enabled us to obtain renal tissue for a diagnostic study in a patient with Korean hemorrhagic fever. The final biopsy report is pending. Specific immunofluorescent staining for the han taan viral antigen was negative. This protocol does not provide access to renal tissue in other patients with Korean hemorrhagic fever. Due to the negative findings of the study, we will not pursue attempts at publication.

Detail Summary Sheet

Date: 9 Jan 85 Prot No: 10/83 Status: Terminated
 TITLE: Bleeding in Myxedematous Rabbits

Start Date: Jan 83		Est Comp Date:
Principal Investigator: MAJ J. Craig Holland, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine		Associate Investigators: LTC Joseph C. Woods, MC
Key Words: Myxedema		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$4,000.	Periodic Review Results: Terminated

OBJECTIVE: To determine if myxedema increases bleeding from heparin.

TECHNICAL APPROACH: No more than 32 rabbits will have thyroidectomies performed and will be followed with T3 and T4 determinations every 30 days. The parathyroid gland is incorporated in the thyroid gland in rabbits, but for unknown reasons hypoparathyroidism is not serious in this species. After the animals meet the definition of hypothyroidism, they will be given graded doses of heparin. After bleeding is established, attempts will be made to reverse the bleeding by treatment with protamine, epsilon amino caproic acid, and coagulation component transfusion.

PROGRESS: Twelve rabbits have had thyroidectomies with 12 controls. The 12 thyroidectomized and 6 control rabbits have been subjected to bleeding times on the ear before and after heparin. No coagulation differences were seen. The study is being discontinued because of negative results.

Detail Summary Sheet

Date: 21 Dec 84 Prot No: 19H/84 Status: Ongoing

TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin

Start Date: Apr 84		Est Comp Date: Nov 86
Principal Investigator: MAJ J. Craig Holland, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Endocrine-Metabolic		Associate Investigators: COL Leonard Wartofsky, MC
Key Words: Graves' ophthalmopathy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Apr 85

OBJECTIVE: To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

TECHNICAL APPROACH: This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

PROGRESS: This is an Army-wide study utilizing all Army Medical Centers. The initial application was approved at Walter Reed Army Medical Center in February 1984. The study's initial progress was completely halted because the Food and Drug Administration and Sandoz Pharmaceuticals were having problems with Cyclosporin protocols that did not deal specifically with organ transplants. By 15 October 1984, this administrative issue had been resolved, an IND number has been issued, and the protocol essentially was started up again at this point.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: HOG 8148(84) Status: Ongoing

Title: 13-Cis-Retinoic Acid in the Treatment of Advanced Carcinoma of the Lung

Start Date: Mar 84		Est Comp Date: Indefinite
Principal Investigator: MAJ William Uphouse, MC		Facility: Tripler Army Medical Center
Dept/Sec: Medicine/Hematology-Oncology		Associate Investigators: COL Jeffrey Berenberg, MC CPT Dominic Solimando, MSC
Key Words: Lung cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Mar 85

OBJECTIVE: To determine the activity of a synthetic Vitamin A derivative called 13-cis-retinoic acid in treating patients with advanced lung cancer who have failed prior chemotherapy and for whom radiation is not appropriate. If there is any available tumor tissue that was resected in the past, this may be submitted for Vitamin A receptor protein levels.

TECHNICAL APPROACH: Patients with advanced lung cancer who have failed prior chemotherapy will receive 13-cis-retinoic acid by mouth daily until their cancer progresses.

PROGRESS: A total of four patients have been entered on this study, two from Tripler. The two non-Tripler patients died before any response could possibly be assessed. One Tripler patient stabilized his rapidly progressive disease for two months. The other Tripler patient has had no response to treatment.

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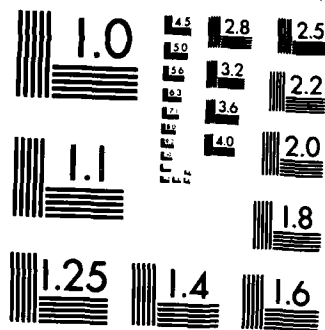
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Detail Summary Sheet

Date: 29 Oct 84		Prot No: HOG 8148(84)		Status: Ongoing	
TITLE: 13-Cis-Retinoic Acid in the Treatment of Advanced Carcinoma of the Lung					
Start Date: Mar 84			Est Comp Date: Indefinite		
Principal Investigator: MAJ William Uphouse, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Medicine/Hematology-Oncology			Associate Investigators: COL Jeffrey Berenberg, MC CPT Dominic Solimando, MSC		
Key Words: Lung cancer					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: To be reviewed in Mar 85	

OBJECTIVE: To determine the activity of a synthetic Vitamin A derivative called 13-cis-retinoic acid in treating patients with advanced lung cancer who have failed prior chemotherapy and for whom radiation is not appropriate. If there is any available tumor tissue that was resected in the past, this may be submitted for Vitamin A receptor protein levels.

TECHNICAL APPROACH: Patients with advanced lung cancer who have failed prior chemotherapy will receive 13-cis-retinoic acid by mouth daily until their cancer progresses.

PROGRESS: A total of four patients have been entered on this study, two from Tripler. The two non-Tripler patients died before any response could possibly be assessed. One Tripler patient stabilized his rapidly progressive disease for two months. The other Tripler patient has had no response to treatment.

Detail Summary Sheet

Date: 21 Dec 84 Prot No: 33/79 Status: Completed
 TITLE: Evaluation of Amiodarone Therapy of Cardiac Arrhythmias

Start Date: Sept 80		Est Comp Date:
Principal Investigator: MAJ Dale C. Wortham, MC		Facility: Tripler Army Medical Center
Dept/Sec: Dept of Medicine/Cardiology		Associate Investigators:
Key Words: Amiodarone Arrhythmia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,140	Periodic Review Results: Completed

OBJECTIVE: To control symptomatic cardiac arrhythmias that have not been responsive to the conventional and accepted forms of treatment or whose control is dependent on the use of a drug that has been shown to be harmful to or in other ways not tolerated by the individual.

TECHNICAL APPROACH: Amiodarone, an investigational drug, is utilized to treat supraventricular and ventricular arrhythmias that are refractory to other drugs. All results are pooled with other Army installations utilizing Amiodarone therapy. The collecting facility for this data is Letterman Army Medical Center.

PROGRESS: The evaluation of Amiodirone therapy of cardiac arrhythmias has been discontinued. The only active patient on the protocol had his medications stopped because of abnormal liver function tests, and the insertion of a permanent pacemaker. Should the need for this medication arise again, it will be obtained through an alternate method.

The evaluation of Amiodirone therapy of cardiac arrhythmias has been terminated. The only active patient on the protocol had his medications stopped because of abnormal liver function tests, and the insertion of a permanent pacemaker. Should the need for this medication arise again, it will be obtained through an alternate method.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 23/82	Status: Ongoing
TITLE: Pregnancy Outcome as a Function of Mild Exercise or No Exercise During Pregnancy in Active Duty Military Women		
Start Date: Feb 83	Est Comp Date: Jan 85	
Principal Investigator: MAJ Deborah A. Bopp, ANC	Facility: Tripler Army Medical Center	
Dept/Sec: Obstetrics and Gynecology	Associate Investigators:	
Key Words: Exercise Pregnancy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To compare the effects of a required mild exercise program to exercise profile during pregnancy on the course of and complications of postpartum recovery.

TECHNICAL APPROACH: This is a study comparing pregnant active duty women who are profiled against physical training and a group of active duty women involved in and required to attend a pregnancy related physical training program.

PROGRESS: All patients have delivered. Forty-three charts have been reviewed in the study group. Thirty-eight charts have been reviewed in the control group. Awaiting other charts which are currently not available.

Detail Summary Sheet

Date: 7 Nov 84		Prot No: 2/83		Status: Completed	
TITLE: Coronary-Prone Behavior Pattern, Life Change Events, and Complications in Pregnancy					
Start Date: Jan 83			Est Comp Date:		
Principal Investigator: CPT Patricia D. Coussens, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Obstetrics and Gynecology			Associate Investigators: CPT Wayne R. Coussens, MSC		
Key Words: Coronary-prone behavior pattern Life change events Pregnancy complications					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$500.		Periodic Review Results: Completed	

OBJECTIVE: To assess the relationship between coronary-prone behavior patterns, recent stress life events, and development of complications in pregnancy and to determine the degree to which early measurement of coronary-prone behavior pattern and life change events are predictive of pregnancy complications.

TECHNICAL APPROACH: Volunteer primiparous obstetric patients will complete the Jenkins Activity Survey (JAS), the Holmes-Rahe Social Readjustment Rating Scale (SRRS), and a demographic questionnaire at least 4 weeks prior to their due date. The JAS classifies coronary-prone (Type A) or non-coronary prone (Type B) patients. The SRRS reflects the number of stressful life events experienced. Patients will be categorized by life stress (LS) levels plus coronary prone (CP) levels (example high LS, high CP, mod LS, low CP, etc.). Rates of obstetric complications, kinds of delivery, required analgesia/anesthesia, etc., will be compared for the various categories of patients using chi square multiple analysis and ANOVAS.

PROGRESS: Over 60 of the 200 patients required to complete the analysis matrix have been entered into this study. Problems have been encountered in obtaining volunteers and complete data sets making this protocol not sufficiently economical to warrant continued efforts. The required patient pool cannot be obtained in sufficient time to permit the 28-week data collection period prior to PCS of the principal and associate investigators. Data now available will be analyzed, but no new subjects will be entered into this study.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: 6A/84 Status: Ongoing

TITLE: Investigation of Factors Affecting Implantation of in vitro Fertilized Mouse Embryos

Start Date: Dec 83		Est Comp Date: Nov 85
Principal Investigator: MAJ Steven T. Dodge, MC		Facility: Tripler Army Medical Center
Dept/Sec: Obstetrics and Gynecology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: To be reviewed in Dec 85

OBJECTIVE: To determine the optimal conditions for successful implantation of in vitro fertilized mouse embryos.

TECHNICAL APPROACH: The protocol has been modified so that initial stages will be with in vivo fertilized mouse embryos. Blastocyst mouse embryos will be transferred from donor to recipient females by a nonsurgical transcervical approach. Initially, the effect of superovulation of recipients on implantation rates will be studied. Later, the effects of hormones and other additives to culture media can be studied.

PROGRESS: Progress has been delayed by the following problems: (a) incubator problems, now corrected; (b) water and culture media problems; now solved by use of commercially-prepared Earle's media (Gibco), and (c) animal facility disaster, mice were not fed over one weekend in May 84, and as a result, the majority of breeding stock of CF-1 mice was lost. CD-1 strain was ordered as replacement and only recently has the number of young produced been sufficient for experimentation.

Success thus far: "Dress rehearsal" in the last week of September involved the transfer of 72 embryos to 6 recipients. Three females became pregnant and delivered 10 pups.

Experiment in progress: In Oct, 80 embryos were transferred to 8 females of the control group. Plan is for similar transfer every 3 weeks to experimental groups (recipients superovulated with 5 IU, 10 IU, and 20 IU PNMSG).

Detail Summary Sheet

Date: 29 Oct 84	Prot No: GOG 26(84)	Status: Ongoing
TITLE: A Phase II Trial of Progesterone in the Treatment of Advanced or Recurrent Epithelial Ovarian Cancers That Have Failed Combination Chemotherapy		
Start Date: Jun 84	Est Comp Date: Indefinite	
Principal Investigator: MAJ Enrique Hernandez, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Obstetrics and Gynecology	Associate Investigators: COL Kunio Miyazawa, MC COL Edward N. Raleigh, MC COL Sam Shannon, Jr., MSC	
Key Words: Cancer, ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Jun 85

OBJECTIVE: To determine whether epithelial ovarian cancer will respond to treatment with a hormone, C.T. Provera, administered by mouth as three tablets daily.

TECHNICAL APPROACH: Patients with epithelial ovarian carcinoma who have progressed on a first-line combination chemotherapy regimen consisting of at least two drugs will be eligible for the study. Estrogen and progesterone receptor determinations will be obtained of tumor removed at the time of primary surgery, second-look laparotomy, or from biopsy of external lesions. To be eligible, patients must have measurable disease. After informed consent, the patient will be registered with the Gynecologic Oncology Operations Office. The patient will receive C. T. Provera, 50 mg orally, three times a day.

PROGRESS: No TAMC patients have been entered to date.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: GOG 55(84)		Status: Ongoing	
TITLE: Hormonal Contraception and Trophoblastic Sequelae After Hydatidiform Mole, Phase III					
Start Date: Sep 84			Est Comp Date: Indefinite		
Principal Investigator: MAJ Enrique Hernandez, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Obstetrics and Gynecology			Associate Investigators: COL Kunio Miyazawa, MC COL Edward N. Raleigh, MC COL Sam Shannon, Jr., MSC		
Key Words: Trophoblastic disease Contraception					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: To be reviewed in Sep 85	

OBJECTIVE: To determine whether the administration of estrogen-progesterone oral contraceptives following the evacuation of a hydatidiform mole, and prior to the HCG titer reaching undetectable levels, affects the incidence of trophoblastic sequelae requiring chemotherapy.

TECHNICAL APPROACH: Patients with a histologically verified diagnosis of hydatidiform mole with no evidence of metastasis will be randomized within 2 weeks of mole evacuation to hormonal contraception. At the end of 12 weeks, all patients will be evaluated for development or nondevelopment of trophoblastic sequelae. All patients will remain on the study for a minimum of six months after primary evacuation. The patients will be followed with weekly serum Beta-HCG determinations, history, and pelvic examination every 2 weeks and chest x-ray every 4 weeks. The end point will be the development or nondevelopment of trophoblastic sequelae. The patient will be judged to have no trophoblastic sequelae if a single Beta-HCG is negative by 12 weeks post-evaluation and the patient has no clinical evidence of persistent trophoblastic disease.

PROGRESS: No TAMC patients have been entered to date. One eligible patient declined participation.

Detail Summary Sheet

Date: 29 Oct 84		Prot No: GOG 61(84)	Status: Ongoing
TITLE: Phase III Randomized Study of Cisplatin Plus Cyclophosphamide Versus Hexamethylmelamine After Second-look Surgery in Non-measurable Stage III and IV Ovarian Adenocarcinoma Partially Responsive to Previous Regimens Containing Cisplatin and Cyclophosphamide			
Start Date: Apr 84		Est Comp Date: Indefinite	
Principal Investigator: MAJ Enrique Hernandez, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Obstetrics and Gynecology		Associate Investigators: COL Kunio Miyazawa, MC COL Edward N. Raleigh, MC COL Sam Shannon, Jr., MSC	
Key Words: Cancer, ovary Chemotherapy			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Apr 85	

OBJECTIVE: To determine, in non-measurable but residual Stage III ovarian adenocarcinoma partially responsive after treatment with regimens containing Cis-platinum and cyclophosphamide, if the progression-free interval and survival are improved by continuing cyclophosphamide plus Cis-platinum or by changing treatment to hexamethylmelamine.

TECHNICAL APPROACH: Patients with Stage III and IV non-measurable epithelial ovarian cancer, who on second-look laparotomy are found to have residual disease of less or same volume as on the original laparotomy, will be randomized by the GOG Operations Office to Regimens 1 or 2. Regimen 1 consists of Cis-platinum, 50 mg/m², IV, every 3 weeks, plus cyclophosphamide, 1000 mg/m², IV, every 3 weeks. Regimen 2 consists of hexamethylmelamine, 280 mg/m², p.o., in divided daily doses, days 1-14 every 3 weeks, plus pyridoxine, 50 mg, p.o., t.i.d., daily during HMM treatment. The treatment will continue for one year or until progression.

PROGRESS: One TAMC patient has been entered on the protocol. She has completed eight courses of Hexamethylmelamine without unexpected side effects. There is no evidence of disease progression.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: GOG 77(84)	Status: Ongoing
TITLE: A Randomized Study of Carboplatin Versus CHIP in Advanced Carcinoma of the Cervix		
Start Date: Aug 84	Est Comp Date: Indefinite	
Principal Investigator: MAJ Enrique Hernandez, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Obstetrics and Gynecology	Associate Investigators: COL Kunio Miyazawa, MC COL Edward N. Raleigh, MC COL Sam Shannon, Jr., MSC	
Key Words: Cancer, cervix Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85

OBJECTIVE: To determine in a randomized study whether Carboplatin or CHIP has a superior (statistically significant) objective response rate in cervical carcinoma and to assess and compare toxicity (gastrointestinal and renal) of Carboplatin and CHIP.

TECHNICAL APPROACH: Patients who have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix that is resistant to curative treatment with surgery or radiotherapy, and who meet all the eligibility criteria, will be randomized to one of two treatment regimens, receiving either Carboplatin or CHIP.

PROGRESS: No TAMC patients have been entered to date.

Detail Summary Sheet

Date: 19 Dec 84 Prot No: 20H/84 Status: Ongoing

TITLE: Assessment of Prolactin, Vasopressin, Cortisol, and Aldosterone in Amniotic Fluid of Human Fetuses During Gestation

Start Date: May 84		Est Comp Date: Aug 85
Principal Investigator: MAJ Bharat Shah, MC		Facility: Tripler Army Medical Center
Dept/Sec: Obstetrics and Gynecology		Associate Investigators: John R. Claybaugh, Ph.D. Catherine Uyehara Aileen K. Sato
Key Words: Vasopressin; vasotocin; aldosterone; cortisol; prolactin; amniotic fluid; osmolality; human; gestational age		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,000.	Periodic Review Results: To be reviewed in May 85

OBJECTIVE: To correlate amniotic fluid osmolality, prolactin (PRL), vasopressin (ADH), cortisol (CORT), and aldosterone (ALDO) with age of gestation in the normal human fetus and to measure these hormones in conditions of abnormal amniotic fluid volume to determine if there is a possible underlying hormonal basis to the malfunction.

TECHNICAL APPROACH: The fetus has been shown to produce vasotocin in lower mammals. We began with the working hypothesis that vasotocin would be in measurable quantities in the amniotic fluid. The Physiology Service has developed an antisera to vasopressin that cross-reacts with vasotocin almost 100%, and other antisera that do not cross-react. Vasotocin concentration can then be determined by subtraction when these antisera are employed in radioimmunoassay. Other assays are ongoing in the Physiology Service. Amniotic fluid will be collected at two times. Both amniocenteses are a result of the necessity of other tests, i.e., assessment of genetic abnormalities (14-17 weeks) and fetal lung maturity (33-40 weeks). In addition, term amniotic fluid will be collected in conditions of polyhydramnios and oligohydramnios.

PROGRESS: Seventeen specimens have been taken. Prolactin, aldosterone, and cortisol all increase, and osmolality and Na⁺ decrease with gestational age as previously shown by others. We have been able to measure vasotocin and show a decrease; unfortunately, another laboratory published similar findings last month. Verification of the identity of vasotocin by chemical methods has not been reported and we are working on this.

Detail Summary Sheet

Date: 9 Jan 85	Prot No: 21/77	Status: Ongoing
TITLE: Development of Clinical Assays		
Start Date: Sep 77	Est Comp Date:	
Principal Investigator: COL Edward N. Raleigh, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Pathology	Associate Investigators: John R. Claybaugh, Ph.D. COL Samuel A. Cucinell, MC	
Key Words: Clinical assays		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1500.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: This study is designed to (a) familiarize the clinical pathology resident with the field of new and developing assay kits; (b) give him an opportunity to evaluate the various assay kits for cost, effectiveness, and technique; and (c) determine which of the kits would be of greatest service to TAMC.

TECHNICAL APPROACH: All new laboratory tests that become available commercially will be evaluated by sending for information from the manufacturer. A number of kits will be purchased from various manufacturers. Clinical specimens will be obtained from patients with established diagnoses, as well as from appropriate controls. Each kit will be compared for accuracy, sensitivity, ease of performance, cost, shelf life, etc. The investigator will estimate, based on current and future hospital requirements, which test (if any) is best.

PROGRESS: No new assays were tested this year.

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 1/83 Status: Terminated

TITLE: Strep Carrier Study

Start Date: Nov 83		Est Comp Date:
Principal Investigator: MAJ James H. Brien, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Infectious Disease		Associate Investigators: CDR J. E. Fajardo, MC, USN LTC Marvin Krober, MC COL James W. Bass, MC
Key Words: Strep carrier		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$700.	Periodic Review Results: Terminated

OBJECTIVE: To determine the efficacy of clindamycin in eradicating the strep carrier state.

TECHNICAL APPROACH: Initially, all patients were treated with penicillin and monitored with frequent throat cultures at approximately two-week intervals. If the throat cultures stayed negative over the course of six to eight weeks, the patient was released from the study. However, if at any time throughout this period the throat culture turned positive, the patient was entered into a second phase of the study where, by randomization, the patient received either penicillin, clindamycin, or no treatment, and was again followed with frequent throat cultures.

PROGRESS: Of the 39 patients enrolled in the study, 13 were entered into phase 2. Of these, 11 completed participation. Three of the patients completing phase 2 were in the penicillin group, two of which failed to clear the strep from the throat. Four patients were started on Cleocin, all but one of which cleared the strep from the throat. Four patients entered phase 2 on no therapy. Three of these were persistently positive but became negative by the end of their participation in the study; the other one became sick with the strep pharyngitis one month into phase 2 and was taken off the study at that point and placed back on penicillin. This was the only patient taken off due to actual recurrence of infection. While the numbers are not large enough to draw conclusions, preliminary data would indicate that Cleocin rapidly and effectively eliminates the strep in patients who have been persistent strep carriers, whereas treatment with penicillin versus no treatment has essentially the same outcome. No side effects were observed in any treatment group. In April, an accidental loss of power caused many of the specimens to thaw and the study was terminated.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 7837(81) Status: Ongoing

TITLE: Evaluation of Systemic Therapy for Children with T-Cell Acute Lymphatic Leukemia, Phase II

Start Date: Aug 81		Est Comp Date: Indefinite
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Leukemia, T-cell		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the effectiveness of aggressive treatment of T-cell acute lymphatic leukemia and to determine which of two protocols is most effective with the least amount of side effects.

TECHNICAL APPROACH: Children with T-cell leukemia are eligible. Treatment as outlined in the study protocol.

PROGRESS: This protocol was activated 1 Apr 79. Total patient accrual to date is 269. One patient was registered from TAMC in FY 82. This is a modified protocol as of July 1981 with the exclusion of a previous randomized treatment arm #1 because of early poor response as compared to the treatment arm 11. Protocol has continued since July 1981 as a nonrandomized study with particular attention paid to the response of certain T-cell patient subgroups. Results of treatment arms are preliminary at this date with overall 90% induction rate and 50% 30-month survival. Cell marker studies show that ER-, PT+ patients have improved survival over ER+, PT+ patients (70% vs 50% survival, P = 0.01). The study remains open for accrual of new patients.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POC 7799(82) Status: Terminated
 TITLE: Rare Tumor Registry

Start Date: Jan 82	Est Comp Date:
Principal Investigator: LTC Stephen R. Stephenson, MC	Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: MAJ Bruce A. Cook, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.
	Periodic Review Results: May 84/Terminated

OBJECTIVE: To gather information about rare malignancies.

TECHNICAL APPROACH: Any child under the age of 18 at diagnosis.
 Treatment as outlined in the study protocol.

PROGRESS: No patients from TAMC have been entered into this protocol.
 This study has been closed to new patient accrual.

Detail Summary Sheet

Date: 9 Nov 84		Prot No: POG 7660(81)		Status: Completed
TITLE: Comparison of Involved Field Radiotherapy with Adjuvant MOPP Chemotherapy in the Treatment of Stage I and II Hodgkin's Disease, Phase III				
Start Date: Aug 81		Est Comp Date:		
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center		
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC		
Key Words: Hodgkin's disease				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Completed		

OBJECTIVE: To compare two forms of treatment for stage I and stage II Hodgkin's disease.

TECHNICAL APPROACH: Children under 18 with untreated stage I and II Hodgkin's disease were eligible. Patients with massive mediastinal disease requiring local radiotherapy on an urgent basis for tumor shrinkage prior to lymphography and administration of anesthesia for staging celiotomy were eligible. Treatment was as outlined in the study protocol.

PROGRESS: This protocol was closed for entry 29 May 81 due to sufficient patient accrual. National registration totaled 305; one TAMC patient was entered. Survival data indicates less than 5% mortality with very small differences in survival found between the various cell types. Predictably, patients with symptoms had a worse survival rate. Adjuvant MOPP therapy has improved disease-free survival significantly, $P = 0.001$ over Involved Field radiation field and $P = 0.08$ over Extended Field radiation field. Survival is similar in all groups due to the effectiveness of salvage therapy.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 7623(81) Status: Completed

TITLE: Evaluation of Systemic Regimens in the Treatment of Acute Leukemia of Childhood, Phase III

Start Date: Aug 83		Est Comp Date:
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Leukemia, acute, childhood		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To evaluate the desirability of prospective separation of various prognostic groups in ALL for purposes of tailoring treatment regimens to those prognostic factors.

TECHNICAL APPROACH: Patients under 21 years of age at time of diagnosis of ALL, ASL, or AUL, with no previous therapy except for one week or less of corticosteroids prior to admission, falling into a good or poor prognosis category and having either no markers or T-cell markers, were eligible. Treatment was as outlined in the study protocol.

PROGRESS: This protocol was closed for patient entry 27 May 81 due to sufficient patient accrual. Ten TAMC patients were officially entered in this study, none during FY 83. To date, 1,039 patients have been evaluated on this protocol with clinical remission rates of 96% for good prognosis and 83% for poor prognosis patients, and maintained remission of greater than 60% at 36 months for good prognosis and 45% at 36 months for poor prognosis patients. Recent data suggest no statistical differences in toxicity, infection, or remission duration between Bactrim vs no-Bactrim patients. No TAMC patients are currently being treated or followed.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: 12/79 Status: Ongoing

TITLE: Intubation and Chest Tube Placement in Small Laboratory Animals

Start Date: Feb 79		Est Comp Date: Indefinite
Principal Investigator: LTC Franklin Smith, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Neonatology		Associate Investigators:
Key Words: Endotracheal intubation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2500.	Periodic Review Results: May 84/Temporarily Suspend

OBJECTIVE: To provide a teaching model for medical trainees in the proper techniques of endotracheal intubation and chest tube insertion.

TECHNICAL APPROACH: Young kittens and rabbits housed at the Tripler Army Medical Center Animal Facility will serve as animal models. The anatomy of the thorax and airway closely approximates that of the premature human infant. Standard intubation and thoracotomy equipment will be set up at times prearranged with the Department of Clinical Investigation and the Newborn Medicine Service. Junior house staff officers will be provided instruction in proper technique. Each house staff officer will then use the animal models to refine his own abilities.

PROGRESS: This is a recurrent, on-going training project. CPT Steve Pratt, 1st-year fellow in neonatology, is now the principal investigator. In May 84 the protocol was temporarily suspended awaiting the submission of additional information.

Detail Summary Sheet

Date: 1 Nov 84 Prot No: 10H/84 Status: Completed
 TITLE: Gentamicin Therapy in Premature Neonates

Start Date: Feb 84		Est Comp Date:
Principal Investigator: CPT Eduardo J. Lugo, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics		Associate Investigators: LTC Franklin R. Smith, MC LTC James S. Rawlings, MC COL James W. Bass, MC
Key Words: Gentamicin Prematurity Dosage interval		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	
		Periodic Review Results: Completed

OBJECTIVE: To determine the adequacy of serum concentrations of a new gentamicin regimen for premature neonates.

TECHNICAL APPROACH: A previous study by the principal investigator using a gentamicin standard regimen with a fixed-dosage interval showed an inverse linear correlation between peak and trough gentamicin serum concentrations and gestational age (GA). A new gentamicin regimen was formulated based on this correlation using a one-compartment pharmacokinetic model. The regimen consists of a 3.5 mg/kg dose given at an interval determined by the formula of dosage interval (hrs) = $50.5 - 0.76 \text{ GA}$. This regimen is designed to yield peak and trough serum concentrations of 8.0 mcg/ml and 1.5 mcg/ml, respectively.

PROGRESS: Thirty-two premature neonates have been studied (within the first week of life). Mean gestational age has been 31.4 weeks (range 25-30). Mean peak and trough gentamicin serum concentrations (± 50) are 7.0 \pm 1.17 mcg/ml, respectively. All serum concentrations have been within the recommended range. This is the lowest incidence of inappropriate gentamicin serum concentrations in any series reported in the literature. The results so far suggest that relating dosage interval to gestational age in this fashion is a simple and effective way of achieving optimal peak and trough Gentamicin serum concentrations in premature infants.

To be presented at the 20th Annual Uniformed Services Pediatric Seminar, Norfolk, Virginia, in March 1985.

Detail Summary Sheet

Date: 1 Nov 84 Prot No: 23/83 Status: Ongoing
 TITLE: D-Lactate Metabolism in Infants with Necrotizing Enterocolitis

Start Date: May 83		Est Comp Date: Sep 85
Principal Investigator: CPT Eduardo J. Lugo, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Neonatology		Associate Investigators: LTC Franklin R. Smith, MC COL Samuel A. Cucinell, MC MAJ Eldon W. Askew, MC
Key Words: D-lactate metabolism Necrotizing enterocolitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the acid burden from D-lactate in infants with necrotizing enterocolitis (NEC).

TECHNICAL APPROACH: A previous study showed a substantial increase in urinary D-lactate (uDL)/creatinine ratio in infants with NEC as compared to themselves before disease and after recovery, and compared to healthy and high risk infants without NEC. In this study we will study D-lactate (DL) metabolism in six infants with NEC. All patients will undergo diagnostic work-up and management in accordance with currently accepted standards of neonatal intensive care. Urine will be collected and analyzed for DL, creatinine, pH, titratable acid (TA) and osmolality from the onset of illness until recovery. Daily blood studies will include electrolytes, creatinine, DL, pH, pCO₂. The following will be calculated: creatinine clearance, DL² clearance, DL fractional excretion, base deficit and anion gap. Correlations will be made between uDL versus serum DL (sDL); fractional excretion of DL versus shock (blood pressure), acidosis and pharmacology agents; uDL versus TA and urine pH; base deficit versus sDL.

PROGRESS: Two patients have been included in the study. The results have been inconclusive in both patients because of an absence of detectable amounts of D-lactate in the urine.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 30/83	Status: Completed
TITLE: Syndrome of Inappropriate Secretion of Antidiuretic Hormone in Aseptic Meningitis		
Start Date: Aug 83	Est Comp Date:	
Principal Investigator: CDR J. Eduardo Fajardo, MC, USN	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics	Associate Investigators: John R. Claybaugh, Ph.D. CPT Elizabeth Stafford, MC MAJ James H. Brien, MC COL James W. Bass, MC	
Key Words: Antidiuretic hormone Aseptic meningitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2000.	Periodic Review Results: Completed

OBJECTIVE: To determine the frequency, if any, of the syndrome of inappropriate secretion of antidiuretic hormone (SIADH) in patients with aseptic meningitis.

TECHNICAL APPROACH: Urine was extracted from diapers or obtained by spontaneous micturition from patients admitted to the pediatric ward with the diagnosis of meningitis. Samples were obtained upon admission and at 12-hour intervals for 48 hours and processed for the determination of vasopressin and its metabolite by radioimmunoassay and for measurement of osmolality and creatinine. The patients were divided into two groups: bacterial and aseptic meningitis. The results obtained from these two groups were compared with normal values determined in a parallel study and with the results from a third group of controls matched by age and sex formed by patients admitted to the pediatric ward with diagnoses other than meningitis or pneumonia. The personnel performing the laboratory tests were unaware of the diagnoses. The diagnosis of bacterial meningitis depended on cerebrospinal fluid (CSF), pleocytosis, and CSF cultures positive for a bacterial pathogen. Aseptic meningitis was the diagnosis if CSF cultures were negative in the presence of pleocytosis. Viral cultures were also obtained as part of the routine work-up.

PROGRESS: Twenty-two patients were enrolled in this study. Normal variation dependent on age of ADH/creatinine has been determined. Patients with bacterial meningitis show marked increase of ADH excretion; patients with aseptic meningitis show little or no variation of ADH values. Data is being prepared for publication.

Detail Summary Sheet

Date: 30 Oct 84 Prot No: 21/83 Status: Completed
 TITLE: Yersinia enterocolitica and Appendicitis

Start Date: Apr 83		Est Comp Date:
Principal Investigator: CDR J. Eduardo Fajardo, MC, USN		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics		Associate Investigators: COL Peter J. Barcia, MC LTC Viola Brooks, MC COL James W. Bass, MC
Key Words: Appendicitis Yersinia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To define the incidence of Yersinia enterocolitica in the pathophysiology of appendicitis.

TECHNICAL APPROACH: Appendices were cultured in a special medium to determine if Yersinia enterocolitica plays any role in appendicitis. Those patients with positive cultures were contacted to investigate possible sources for this agent.

PROGRESS: A total of 99 patients were enrolled. All cultures were negative for Yersinia. The data obtained have been accepted for publication as a Letter to the Editor in Pediatric Infectious Diseases.

Date: 30 Oct 84 Prot No: 8/83 Status: Completed
 TITLE: Pleural Empyema in Children and Adolescents

Start Date: Jan 83		Est Comp Date:
Principal Investigator: CDR J. Eduardo Fajardo, MC, USN		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics		Associate Investigators: MAJ James Brien, MC LTC Marvin Krober, MC COL James W. Bass, MC
Key Words: Pleural Empyema		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: Completed

OBJECTIVE: To provide a rational basis for the initiation of antimicrobial therapy for patients presenting with pleural empyema.

TECHNICAL APPROACH: The discharge summaries of patients from the neonatal period to 18 years of age, treated for pleural empyema during the last 10 years in the major military hospitals, were analyzed to determine the type of bacterial isolates obtained and predisposing factors to such pathological conditions.

PROGRESS: One hundred four discharge summaries obtained from all military hospitals have been received. Pleural empyema has been found to occur more frequently in males than females (2/1 ratio) and to more frequently be the complication of pneumonia. H. influenzae and streptococcus pneumoniae are the most common causative agents. The information obtain is being prepared for submission for publication.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 15/83	Status: Terminated
TITLE: Comparison of Adverse Reactions of Orally Administered Antibiotics Commonly Used in the Treatment of Acute Otitis Media		
Start Date: Apr 83	Est Comp Date:	
Principal Investigator: CPT Robert W. Enzenauer, MC	Facility: Tripler Army Medical Center	
Dept/Sec: U.S. Army Health Clinic/Pediatrics	Associate Investigators: MAJ A. Shah, MC MAJ S. Brown, MC MAJ V. Barnes, MC MAJ L. Jorgeson, ANC	
Key Words: Otitis media; antibiotic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2,000.	Periodic Review Results: Terminated

OBJECTIVE: To provide information that will aid the clinician in choosing the optimal treatment for patients with acute otitis media.

TECHNICAL APPROACH: Infants and children with newly diagnosed acute otitis media are eligible for the study. The diagnosis of acute otitis media will require the presence of middle ear effusion of acute onset, accompanied by erythema of the drum, loss of the anatomic landmarks, and immobility of the tympanic membrane documented by pneumatic otoscopy. Patients may be omitted from the study for any one of the following reasons: (a) parents do not wish to participate; (b) history of allergy or sensitivity to penicillin or ampicillin; (c) previous acute otitis media in the previous 30 days; or (d) previous antibiotic treatment within 30 days of examination. Children fulfilling the criteria for admission to the study will be treated by randomization with one of six treatment regimens. The treating doctor and the parent will be blind to the regimen used. Only the pharmacist will be aware of the treatment regimen. Parents will be given an information sheet detailing the goals of the study. Parents will complete a data sheet which is to be returned at the ear recheck two weeks after initiation of treatment. All rashes occurring during treatment will be examined by one of the participating study physicians and characterized in detail on the data sheet. Six hundred children will be treated (100 each with each of the six treatment regimens) and evaluated. The data will then be compared and the incidence of untoward reactions associated with each treatment regimen will be defined.

PROGRESS: This study is terminated without completion. Shortly after the project was begun, two of the associate investigators were transferred, and the Principal Investigator was deployed to Honduras for four months. Resulting increased physician workload in Pediatric Clinic precluded adequate time for informed consent counselling of parents.

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 11H/84 Status: Ongoing
 TITLE: Oral Rehydration in Infants and Children

Start Date: Feb 84		Est Comp Date: Jan 86
Principal Investigator: MAJ James H. Brien, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Infectious Disease		Associate Investigators: COL James W. Bass, MC CPT Glenn Edwards, MC CDR J. E. Fajardo, MC
Key Words: Oral rehydration		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Jan 85

OBJECTIVE: To test the efficacy and safety of using an oral solution to rehydrate patients admitted to the pediatric ward with mild to moderate dehydration (less than or equal to 10%). Special emphasis will be placed on determining the economic practicality of this method compared to conventional IV therapy.

TECHNICAL APPROACH: Subjects will consist of children three months to two years of age who are admitted to the pediatric ward with the diagnosis of less than or equal to 10% dehydration of less than five days duration. After obtaining informed consent, the participants will be placed into one of three treatment groups. Group 1 will be those treated with standard IV fluids and will function as the control group. Group 2 will be those receiving Pedialyte RS which is an oral rehydration solution provided by Ross Laboratories, and Group 3 will be those treated with Infalyte, an oral rehydration solution.

PROGRESS: This project was not started due to the departure of the Principal Investigator. CPT Thomas Martinko, MC, CPT Frederick Miller, MC, CPT Dean Dalrymple, MC, and CPT John Lesica will become the investigators on this study.

Detail Summary Sheet

Date: 31 Dec 84 Prot No: 41/83 Status: Terminated
 TITLE: Etiology of Fever in Infants Three to Six Months of Age

Start Date: Nov 83		Est Comp Date:
Principal Investigator: MAJ James H. Brien, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Infectious Disease		Associate Investigators: COL James W. Bass, MC CPT Gary Turner, MC CDR J. Eduardo Fajardo, MC, USN
Key Words: Fever		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To determine the viral and bacterial causes of fever in infants three to six months of age, and to correlate initial clinical and laboratory data with the final diagnosis. The ultimate goal is to be able to distinguish between potentially serious bacterial infections and self-limited viral illnesses early in the course of the disease.

TECHNICAL APPROACH: The criteria for enrollment in the study will be a child between three and six months of age with an acute fever of 38°C (100.4°F) or more rectally. Upon entering the study, bacterial and viral cultures will be obtained on blood, urine, stool, and throat (NP wash for viral). Spinal fluid will be obtained if clinically indicated. An AP and lateral chest x-ray and acute viral titers will also be obtained. Other tests to be done will include CBC, UA, SMA-20, and urinary ADH. Convalescent viral titers will be drawn three to six weeks later. The child will be clinically assessed on admission, at 12 hours, and at 24 hours. All data will be compiled on a flow sheet and subjected to statistical analysis.

PROGRESS: There has been only one patient enrolled in the study who fulfilled the criteria, and the result of his workup was an adenovirus infection. The project is terminated due to the departure of the Principal Investigator.

Detail Summary Sheet

Date: 31 Dec 84	Prot No: 29/83	Status: Completed
TITLE: Quantitation of Group A Beta Hemolytic Streptococci Recovered From Various Areas of the Oropharynx in Patients with Streptococcal Pharyngitis		
Start Date: Jul 83	Est Comp Date:	
Principal Investigator: MAJ James H. Brien, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics/Infectious Disease	Associate Investigators: CDR J. Eduardo Fajardo, MC, USN LTC Marvin S. Krober, MC COL James W. Bass, MC	
Key Words: Streptococcal pharyngitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$700.	Periodic Review Results: Completed

OBJECTIVE: To determine the best area in the mouth or oropharynx to obtain a culture and have the best chance of recovering group A beta hemolytic strep in those patients infected with that organism.

TECHNICAL APPROACH: A total of eight areas in the mouth and oropharynx were cultured, including the posterior pharyngeal wall tonsil, buccal mucosa, posterior and anterior tongue, sublingual area, anterior sulcus and palate. A specimen of the patient's saliva was also obtained. The degree of positive cultures for group A beta hemolytic strep ranging from negative to 4+ were documented by colony count and the data were collated according to the geographic area from which the cultures were obtained.

PROGRESS: This study has recently reached completion with only 12 patients entered in it. However, the results were dramatic enough that further work appeared to be unnecessary. The results clearly indicate that there are only two acceptable sites from which to obtain throat cultures in patients suspected of having Group A Beta hemolytic streptococcal pharyngitis. These are the tonsil or the posterior pharyngeal wall. Due to the high false-negative rate of Group A Beta hemolytic streptococcal in virtually all the other anatomic sites and saliva, no other alternative should be considered as an appropriate site to culture. A manuscript is in preparation.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 7898(82) Status: Ongoing
 TITLE: Intergroup Rhabdomyosarcoma Study-II

Start Date: Jan 82		Est Comp Date: Indefinite
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Rhabdomyosarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To compare two forms of treatment. At the present time there is no evidence that either of these treatment programs is superior and the purpose of the study is to compare the response to treatment, duration of disease control, and side effects which result from the treatment.

TECHNICAL APPROACH: All patients 21 years of age or under with diagnosis of rhabdomyosarcoma or of undifferentiated sarcoma are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: This protocol was activated 1 Nov 78. Total patient accrual to date is 1017. Two patients have been registered from TAMC. In general, for nonmetastatic disease there is no significant difference in survival over the previous protocol. The actual survival rate for both Stage I and II approaches 100%. For advanced rhabdomyosarcoma the more aggressive staging and chemotherapeutic treatment regimens adopted in IRS-II are showing significant improvement in survival although data is as yet incomplete. There is no difference between the two treatment arms; therefore, Adriamycin did not improve prognosis in this study.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 7905(81) Status: Completed
 TITLE: A-COP Plus for Non-Hodgkin's Lymphoma in Children, Phase III

Start Date: Aug 81		Est Comp Date:
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Lymphoma, non-Hodgkin's		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To determine the effect of the combination of chemotherapy and radiation therapy on non-Hodgkin's lymphoma and to determine which of two protocols is more effective with the least side effects.

TECHNICAL APPROACH: Children with non-Hodgkin's lymphoma were eligible. Treatment was as outlined in the study protocol.

PROGRESS: This protocol was activated 25 May 79. Total patient accrual to date is 205. Two patients have been registered from TAMC and are being followed but not treated. The study is now closed since sufficient numbers have been accrued for statistical evaluation. Results to date reveal that ACOP+ is more effective and less toxic than LSA2-L2 in nonlymphocytic types of lymphoma. This is very striking in the histiocytic subtype where ACOP+ was superior to LSA2-L2 (61% vs 22% P = 0.001) at 2-3 years.

Detail Summary Sheet

Date: 9 Nov 84		Prot No: POG 7909(82)		Status: Ongoing	
TITLE: Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma.					
Start Date: Jan 82			Est Comp Date: Indefinite		
Principal Investigator: LTC Stephen R. Stephenson, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Pediatrics/Hematology-Oncology			Associate Investigators: MAJ Bruce A. Cook, MC		
Key Words: Medulloblastoma Ependymoma					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: May 84/Continue	

OBJECTIVE: To study the effect of surgery and radiation therapy on medulloblastoma or ependymoma and to determine whether the addition of the MOPP chemotherapy drugs to the surgery and radiation therapy improves the success rate in treating these tumors.

TECHNICAL APPROACH: Children diagnosed as having medulloblastoma or ependymoma are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No TAMC patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 8000(81) Status: Ongoing
 TITLE: The National Wilms' Tumor Study III

Start Date: Aug 81		Est Comp Date: Indefinite
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Wilms' tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the effect of chemotherapy of Wilms' tumor and to determine which chemotherapy schedule is best. This study is also designed to determine if radiation therapy is necessary when the tumor has been completely removed and in what dosage.

TECHNICAL APPROACH: Children diagnosed as having Wilms' tumor are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: This is a national protocol comprised of patients from several cancer study groups. As such, the data represent cumulative figures for these various groups and not specifically for POG patients. This protocol was activated 5 Jan 79. As of May 1983, 1,300 patients have been registered, of which 40% have completed two years on study. Three patients have been registered from TAMC, none in FY 84. This important study has demonstrated several important advances that will allow less therapy to be given to Wilms' tumor patients. (1) Stage I patients do well with only 10 weeks vs 6 months of therapy. (2) Radiotherapy does not improve results in Stage II or III patients. (3) In Stage III patients, the addition of a third drug (Adriamycin) improves survival. However, 1000R is as effective as 2000R in local disease control. (4) In Stage IV disease, a 3-drug regimen is as effective as a 4-drug regimen.

Detail Summary Sheet

Date: 9 Nov 84			Prot No: POG 8035/36(82)			Status: Ongoing		
TITLE: Laboratory Subclassification and Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (AlinC #13)								
Start Date: Jan 82					Est Comp Date: Indefinite			
Principal Investigator: LTC Stephen R. Stephenson, MC					Facility: Tripler Army Medical Center			
Dept/Sec: Pediatrics/Hematology-Oncology					Associate Investigators: MAJ Bruce A. Cook, MC			
Key Words: Leukemia, acute lymphoid								
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost: \$300.			Periodic Review Results: May 84/Continue		

OBJECTIVE: To compare the results of treatment of the various subtypes.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: This protocol was activated (opened for patient entry) 29 May 81 and revised 20 Nov 81. Total patient accrual to date is 1,266. Two TAMC patients have been registered, both in FY 82. Data from this extremely complicated protocol is just beginning to be analyzed. Subclassification data has yielded valuable prognostic information concerning lymphocyte subgroups such as B-cell ALL. The major thrust of the protocol continues to be to correlate laboratory subgrouping of acute lymphoid leukemias with response to therapy and tailoring of therapy to deal with those subgroups that are recognized to have a poorer prognosis. Subtype incidence: "null", 64%; Pre B, 18%; T, 16%; B, 2%. Complete remission rates: good risk, 97%; poor risk, 93%.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 8047(83) Status: Completed
 TITLE: Histiocytosis X in Bone

Start Date: Jan 82		Est Comp Date:
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Histiocytosis X		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Completed

OBJECTIVE: To determine the effectiveness of surgery followed by radiation therapy.

TECHNICAL APPROACH: All pediatric and adolescent patients, regardless of age, with histiocytosis X were eligible. Treatment was as outlined in the study protocol.

PROGRESS: This protocol was activated nationally on 19 Mar 81. Eighteen patients have been registered nationally, one from TAMC in FY 82. Thus far, there has been no specific data analysis due to slow patient accrual. To date, 80% of patients are NED after curettage alone. Fifty percent of those with progressive disease responded to low dose radiation therapy (600R). The study is now closed to new patients. No TAMC patients are being treated or followed.

Detail Summary Sheet

Date: 9 Nov 84	Prot No: POG 8101(82)	Status: Ongoing
TITLE: Acute Nonlymphocytic Leukemia (ANLL) in Children, (Phase III)		
Start Date: Jan 82	Est Comp Date: Indefinite	
Principal Investigator: LTC Stephen R. Stephenson, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: MAJ Bruce A. Cook, MC	
Key Words: Leukemia, nonlymphocytic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the effect of combination chemotherapy and radiation therapy to the brain on acute nonlymphocytic leukemia and to determine which of the combinations gives the best results with the fewer side effects.

TECHNICAL APPROACH: Patients less than 21 years of age with the diagnosis of acute leukemia other than lymphoblastic are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: This study was activated 20 Jun 81 and 99 patients have been accrued. Two patients were entered from TAMC in FY 83. To date, induction arm 1 has been shown to be superior over the non-anthracycline induction arm 2 (87% vs 69%). Induction arm 2 has been deleted. It is too early to evaluate the effect of the maintenance regimens.

Detail Summary Sheet

Date: 9 Nov 84		Prot No: POG 8104(83)		Status: Ongoing	
TITLE: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III					
Start Date: Oct 83			Est Comp Date: Indefinite		
Principal Investigator: LTC Stephen R. Stephenson, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Pediatrics/Hematology-Oncology			Associate Investigators: MAJ Bruce A. Cook, MC		
Key Words: Neuroblastoma					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: May 84/Continue	

OBJECTIVE: Attempts to reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy, etc.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under the age of 18 with neuroblastoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

PROGRESS: This study was activated nationally on 20 Nov 81. To date, 278 patients have been entered, four from TAMC in the FY 84. This is a very complex study with seven subcategories of treatment. To date, the induction rates for the two chemotherapy regimens are very similar. Stage A patients have done very well with only 5% relapsing following surgery and staging.

Detail Summary Sheet

Date: 9 Nov 84	Prot No: POG 8106(83)	Status: Ongoing
TITLE: High-Dose Cyclophosphamide/High-Dose Methotrexate with Coordinated Triple Intrathecal Therapy for Stages III and IV Nonlymphoblastic Lymphoma		
Start Date: Nov 82	Est Comp Date: Indefinite	
Principal Investigator: LTC Stephen R. Stephenson, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: MAJ Bruce A. Cook, MC	
Key Words: Lymphoma, nonlymphoblastic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Ongoing

OBJECTIVE: To determine the effect of high-dose cyclophosphamide/high-dose methotrexate with coordinated triple intrathecal therapy for stages III and IV nonlymphoblastic lymphoma.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age with stage III and IV nonlymphoblastic lymphoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

PROGRESS: This protocol was activated nationally on 20 Jan 82 and has accrued 89 patients. Two TAMC patients were registered in FY 83. There are only very preliminary results available at this time. Induction results reveal 64% CR and 30% PR. Severe induction toxicity has led to the altering of induction chemotherapy by decreasing the high dose Cytosan to a single dose each cycle.

Detail Summary Sheet

Date: 9 Nov 84	Prot No: POG 8107(83)	Status: Ongoing
TITLE: Multi-Institutional Controlled Trial of Adjuvant Chemotherapy in the Treatment of Osteosarcoma, Phase III		
Start Date: Aug 83	Est Comp Date:	
Principal Investigator: LTC Stephen R. Stephenson, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics/Hematology-Oncology	Associate Investigators: MAJ Bruce A. Cook, MC COL Peter J. Barcia, MC	
Key Words: Osteosarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the role of chemotherapy in the treatment of this disease, and to determine the best timing of chemotherapy.

TECHNICAL APPROACH: Pediatric patients under 18 years of age with osteosarcoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

PROGRESS: This very important study was opened nationally on 20 Jun 82 and has accrued 133 patients. One TAMC patient was entered in FY 84. Disease-free survival is already very significant with 75% of chemotherapy patients versus 20% of the surgery only patients remaining free of metastatic disease.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 8140(83) Status: Ongoing
 TITLE: Cis-Platinum in Recurrent Brain Tumors, Phase II

Start Date: Aug 83		Est Comp Date: Indefinite
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Brain tumor, recurrent		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the effectiveness, if any, of the chemotherapy drug Cis-Platinum on brain tumors that have recurred after previous therapy.

TECHNICAL APPROACH: Pediatric patients under the age of 18 years who have recurrent brain tumor. Treatment will be as outlined in the study protocol.

PROGRESS: No TAMC patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 8158(83) Status: Ongoing
 TITLE: NWTs Long Term Follow-up Study

Start Date: Aug 83		Est Comp Date: Indefinite
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC
Key Words: Wilms' tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To examine the late consequences of successful treatment given for Wilms' tumor.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor. Treatment will be as outlined in the study protocol.

PROGRESS: No TAMC patients have been entered into this protocol as yet.

Detail Summary Sheet

Date: 19 Dec 84 Prot. No: POG 8232(84) Status: Terminated

TITLE: A Trial of Doxorubicin in Recurrent Ependymoma and Medulloblastoma, Phase II

Start Date: Jun 84		Est Comp Date:
Principal Investigator: LTC Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC CPT Dominic Solimando, MSC
Key Words: Ependymoma Medulloblastoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To determine whether or not doxorubicin is a safe and effective drug in treating recurrent medulloblastoma and ependymoma.

TECHNICAL APPROACH: Children with recurrent medulloblastoma or ependymoma that has been resistant to standard treatment. Treatment will be as outlined in master protocol.

PROGRESS: This protocol is now closed to patient entry. No TAMC patients were entered.

Detail Summary Sheet

Date: 9 Nov 84	Prot No: POG 8261(83)	Status: Ongoing
TITLE: Evaluation of Response and Toxicity of VP-16-213 in Children with Recurrent Malignant Solid Tumors Unresponsive to Standard Therapy, A Phase II Study.		
Start Date: Aug 83	Est Comp Date: Indefinite	
Principal Investigator: LTC Stephen R. Stephenson, MC	Facility: Tripler Army Medical Center	
Dept./Sec: Pediatrics/Hematology-Oncology	Associate Investigators: MAJ Bruce A. Cook, MC	
Key Words: Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To evaluate response and toxicity of this drug in children with recurrent malignant solid tumors unresponsive to standard therapy.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No TAMC patients have been enrolled in this study.

Detail Summary Sheet

Date: 6 Dec 84 Prot No: 17/78 Status: Ongoing

TITLE: Human Implantation of Intraocular Lenses

Start Date: Aug 78		Est Comp Date: Indefinite
Principal Investigator: LTC Joseph B. Barron, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/Ophthalmology		Associate Investigators: LTC William R. Rimm, MC LTC Anthony P. Martyak, MC
Key Words: Intraocular lenses		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: May 84/Continue

OBJECTIVE: To study the effects of implantation of intraocular lenses in humans.

TECHNICAL APPROACH: Utilization of posterior chamber intraocular lenses requires an extracapsular cataract method with preservation of the posterior lens capsule. Anterior chamber intraocular lenses are used after a routine intracapsular cataract extraction, as secondary implants, and when the posterior capsule is broken during an extracapsular cataract procedure.

PROGRESS: During FY 84, 84 intraocular lenses were implanted in humans. Of these, 28 were anterior chamber lenses and 56 were posterior chamber lenses. Eighty-two of the implants were done primarily at the time of the original surgery, and two anterior chamber implants were secondary implants, i.e., placed sometime after the original cataract surgery. Two anterior chamber lenses were removed during the year, one due to an UGH syndrome that was precipitated by a persistent hyphema and uveitis, and the other due to excessive rotation of the intraocular lens caused by improper sizing.

Detail Summary Sheet

Date: 7 Jan 85 Prot No: 7A/84 Status: Ongoing

TITLE: Localization and Toxicity of Ferromagnetic Ceramic Beads (FMCB) in Rabbits

Start Date: Oct 83		Est Comp Date: Oct 85
Principal Investigator: COL Peter J. Barcia, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/General Surgery		Associate Investigators: COL Samuel A. Cucinell, MC Dr. Arnold Feldman
Key Words: Ferromagnetic ceramic beads		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To obtain proper size, dose, injection medium, tissue Localization, and toxicity of FMCB.

TECHNICAL APPROACH: Interest in heat treatment of cancer has been growing. It is possible that magnetic microbeads injected into a cancer will increase the local temperature when exposed to a high frequency magnetic field. These beads are available and preliminary toxicity studies are necessary.

PROGRESS: Awaiting approval of gift acceptance from HSC.

Detail Summary Sheet

Date: 30 Oct 84 Prot No: 6/77 Status: Terminated
 TITLE: Regrowth of Small Intestinal Mucosal Surface Area

Start Date: Nov 76		Est Comp Date: Sep 85
Principal Investigator: COL Peter J. Barcia, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/General Surgery		Associate Investigators:
Key Words: Small intestinal mucosal surface Neogut		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$5,000.	Periodic Review Results: May 84/Terminate

OBJECTIVE: To explore methods of increasing small intestinal mucosal absorptive area following massive resections, and to determine the technical feasibility and functional results of certain specific procedures.

TECHNICAL APPROACH: Based on previous successful studies in dogs and rats with growth of neogut on the serosal surface of the colon, the next step will be to (1) perform similar studies in the pig (which has a gastrointestinal tract and physiologic responses similar to man); and (2) attempt growth of neogut on the peritoneal surface of the abdominal wall. This would mirror the clinical circumstance if no suitable colonic recipient site was available. Five pigs will undergo laparotomy under general anesthesia and each animal will have two grafts placed. After varying periods of time (maximum 8-12 weeks), at a second procedure these grafts could be harvested and intestinal continuity would be restored.

PROGRESS: An initial series of dogs has provided the following data: (1) A new small intestinal mucosa will grow across the serosa of the colon under these circumstances; (2) the graft is mechanically functional, i.e., food is propelled in a relatively normal fashion through the graft, and these animals do not develop small intestinal obstruction. Since no work has been done on this protocol for the past several years, it is terminated.

Detail Summary Sheet

Date: 12 Dec 84	Prot No: 32/83	Status: Ongoing
TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen		
Start Date: Aug 83	Est Comp Date: Aug 85	
Principal Investigator: CPT James A. Ameika, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/General Surgery	Associate Investigators: CPT Harry C. Weiser, MC COL Peter J. Barcia, MC	
Key Words: Urinary D-lactate Acute abdomen		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To determine the usefulness of urinary D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until 4 collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, 10 adults and 10 children will have these specimens collected once preoperatively to serve as controls.

PROGRESS: Data collection has not yet begun. New interns and residents are being briefed on the procedures of data collection. Equipment and supplies are available and it is anticipated that data collection will now begin.

Detail Summary Sheet

Date: 29 Oct 84 Prot No: 1T/84 Status: Terminated

TITLE: Perfecting Angiographic Technique

Start Date:		Est Comp Date:
Principal Investigator: MAJ Stephen M. Holmes, ...		Facility: Tripler Army Medical Center
Dept/Sec: Radiology		Associate Investigators:
Key Words: Angiography		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To perfect radiological technique of percutaneous transhepatic portal venography.

PROGRESS: Terminated. Poor fluoroscopic resolution on large pigs did not allow adequate visualization to carry out study.

Detail Summary Sheet

Date: 21 Dec 84	Prot No: 31/83	Status: Ongoing
TITLE: Enhancing Visualization of Small Nodules in Radiographic Examinations		
Start Date: Jul 83	Est Comp Date: Sep 85	
Principal Investigator: CPT Robert J. Matthews, MSC	Facility: Tripler Army Medical Center	
Dept/Sec: Radiology	Associate Investigators: MAJ Marvin E. Hill, MC	
Key Words: Nodules		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,500.	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To enhance visualization of small nodules in a radiographic examination. These nodules carry diagnostically important information and an improved image will allow this information to be more easily seen. The approach entails the design and construction of an imaging device capable of retrieving resolution lost as a result of the x-ray imaging technique.

TECHNICAL APPROACH: The "true" intensity distribution in a radiographic image in the plane of interest is to be retrieved by a deconvolution of the image in the actual recording with the experimentally derived spread function. The project involves the construction of a deconvolution filter to be used in an analog viewing apparatus that will permit a posteriori sharpening of defocused images notably in the absence of noise. By increasing the signal to noise level in the final image, noise limited structures, such as small chest nodules, may be more easily seen.

PROGRESS: Physical optical laboratory equipment necessary to the project has been received. The experimental spread function has been tentatively chosen to be the hypocycloidal used commonly in conventional tomography. Initial investigations indicate that the spread function is readily recorded by use of an x-ray pinhole camera available in the Department of Radiology. A suitable phantom to produce experimental images is under investigation. A study was initiated to determine qualitatively on theoretical grounds the noise advantages of the deconvolution process proposed in this project. The application of the results to the imaging system analysis is expected to indicate an optimization of deconvolution radiography with respect to image signal to noise ratio.

Detail Summary Sheet

Date: 21 Dec 84	Prot No: 16H/84	Status: Ongoing
TITLE: Stressors, Coping Mechanisms, and Prevalence of Stress-Related Symptoms Among Special Forces (Green Beret) Personnel Who Served One to Several Tours in the Republic of South Vietnam and/or Similar Assignments in Southeast Asia		
Start Date: Apr 84	Est Comp Date: Sep 85	
Principal Investigator: CPT Gary K. Neller, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Psychiatry	Associate Investigators: CPT Victor Stevens, MC Claude Chemtob, Ph.D. COL Dionisios P. Devaris, MC	
Key Words: Stressors Coping mechanisms Stress-related symptoms		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: To be reviewed Mar 85

OBJECTIVE: (1) To assess the presence of stress-related symptoms among Special Forces (Green Beret) soldiers both officers and non-commissioned officers (lowest rank was E-4 in TBA). (2) To assess the relationship of coping styles to the presence or absence of stress-related symptoms.

TECHNICAL APPROACH: Questionnaire and interviews of approximately 30 Special Forces personnel who served one to several tours in the Republic of South Vietnam or a similar assignment in Southeast Asia will be utilized.

PROGRESS: One hundred forty questionnaires have been sent out with 60 questionnaires returned to date. These will be evaluated in the near future.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 42/83	Status: Completed
TITLE: The Influence of Cultural Values on Psychotherapy with Adolescents		
Start Date: Oct 83	Est Comp Date: May 84	
Principal Investigator: LTC James T. Howard, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Psychiatry/Child & Adolescent Psychiatry	Associate Investigators: David Weiss, Ph. D.	
Key Words: Adolescent psychotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1000.	Periodic Review Results: Completed

OBJECTIVE: To determine whether adolescent patients who receive psychotherapy from therapists with similar cultural values improve more than adolescent patients who receive psychotherapy from therapists with dissimilar cultural values.

TECHNICAL APPROACH: Prior to their first session with a therapist, the patients were administered the value orientation profile (VOP) and the Offer Self-Image Questionnaire for Adolescents (OSIQ). Each therapist completed a demographic questionnaire after their contact with the patients. Patients were randomly assigned. This followed normal clinical procedure, which is basically random. Therapists who were staff members in Child and Adolescent Psychiatry Service (CAPS) were assigned patients on a rotating basis after the Fellows had been assigned patients. At the 12th or last evaluation/therapy session, whichever occurred first, the patients were administered the OSIQ and VOP again and the Psychotherapy Questionnaire, Patient Form (PQP), and the therapists completed the Psychotherapy Questionnaire, Therapist's Form (PQT). At the end of the research study, the therapists were administered the VOP.

PROGRESS: Six psychotherapists were involved as therapist subjects. Fifty-six adolescents (ages 13 to 18 years) were screened over 7 months (Oct 83 to May 84). Twenty-eight patient subjects were enrolled in the project and completed the pretest forms. Six patient subjects completed the post-test forms.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 9H/84	Status: Terminated
TITLE: The Comparison of Targeted Group Therapy Compared to Unfocused Therapy for Active Duty Nonpsychotic Inpatients		
Start Date:	Est Comp Date:	
Principal Investigator: CPT Michael G. Herriott, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Psychiatry	Associate Investigators: CPT Steven P. Jewett, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Terminated

OBJECTIVE: To determine if a special inpatient psychiatric program for the nonpsychotic military inpatient improves retention and performance.

TECHNICAL APPROACH: The study was designed to use group therapy as the primary tool to return nonpsychotic patients to active duty.

PROGRESS: This protocol has been terminated due to the departure of the principal investigator.

Detail Summary Sheet

Date: 21 Dec 84	Prot No: 34/83	Status: Ongoing
TITLE: Stressors, Coping Mechanisms, and Prevalence of Stress-Related Symptoms Among Active Duty Military Personnel Who Served in Vietnam		
Start Date: Aug 1984	Est Comp Date: Aug 86	
Principal Investigator: COL Dionisios P. Devaris, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Psychiatry	Associate Investigators: Claude Chemtob, Ph.D. CPT Ken Hoffman, MC MAJ William Weitz, MSC	
Key Words: Stressors Coping mechanisms		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: Sep 84/Continue

OBJECTIVE: (1) To assess the presence of stress-related symptoms among medical enlisted soldiers and officers who served in Vietnam. (2) To assess the relationship of coping styles to the presence or absence of stress-related symptoms.

TECHNICAL APPROACH: Fifty TAMC medical personnel who have served in Vietnam will be interviewed using a semistructured interview format. Subjects will be initially contacted by letter, with a follow-up low-key phone call offering more details, clarification, and opportunity for prospective subjects to ask questions.

PROGRESS: A mailing list has been prepared. A sample mailing has been made with follow-up phone calls and biographic data obtained. It is anticipated that interviews will begin in February 1985.

Detail Summary Sheet

Date: 31 Dec 84	Prot No: 43/83	Status: Ongoing
TITLE: Behavioral Management Versus Drug Therapy in the Treatment of Behavioral Distress Associated with Painful Medical Procedures in Pediatric Oncology Patients		
Start Date: Nov 83	Est Comp Date: Jun 85	
Principal Investigator: MAJ James N. Bowen, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Psychiatry/Child & Adolescent Psychiatry	Associate Investigators: LTC Stephen Stephenson, MC David S. Weiss, Ph.D. Robert Wilkerson, M.D.	
Key Words: Behavioral management		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Sep 84/Continue

OBJECTIVE: To investigate the relative efficacy of a behavior modification program versus drug therapy (pentobarbital or a combination of Demerol, Thorazine, and Phenergan) in reducing behavioral distress (pain and anxiety) in children with cancer undergoing painful medical procedures (lumbar puncture (LP) and bone marrow aspiration (BMA)).

TECHNICAL APPROACH: This study will investigate the effects of a behavioral management program (B) versus drug therapy (D) in the reduction of behavioral distress in pediatric oncology patients. Patients will be blocked into groups based on their age, sex, prior treatment, and OSBD baseline score, and randomly assigned to either the B or D treatment group. Dependent measures will be administered pre, post, and follow-up. Participants will be children aged 4 to 15 years who undergo intermittent BMA and LP as part of their treatment protocols. Dependent measures will measure behavioral distress along several response modalities. In order to assess which children respond, a number of potential predictor variables will be administered.

PROGRESS: Project not yet underway.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 35/83	Status: Ongoing
TITLE: Prophylactic Therapy with Oral Gamma Globulin in the Prevention of Neonatal Necrotizing Enterocolitis: A Controlled Prospective Trial		
Start Date: Jul 83	Est Comp Date:	
Principal Investigator: MAJ Thomas Wiswell	Facility: Tripler Army Medical Center	
Dept/Sec: Pediatrics/Neonatology	Associate Investigators: LTC Franklin Smith, MC CPT Eduardo Lugo, MC	
Key Words: Necrotizing enterocolitis Gamma globulin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine if oral prophylactic therapy with human serum immune globulin, in infants at risk, decreases the incidence of necrotizing enterocolitis (NEC).

TECHNICAL APPROACH: Three hundred consecutive infants at risk for developing NEC will be enrolled. Infants will be randomly assigned to either the placebo group or the gamma globulin therapy group. Duration of therapy will be 10 days or when NEC occurs. Infants with stage I NEC will continue to receive the study solutions; if stage II or III NEC is present, the study will be terminated in that particular infant. Stool and gastric aspirant cultures will be collected from each infant before the first dose of the study and at days 3, 10, and 14 following enrollment. Data obtained will be evaluated for the effects of therapy on incidence and severity of NEC, changing patterns in gastric/stool flora with therapy, and changing patterns of serum immunoglobulin levels with therapy.

PROGRESS: Dr. Wiswell has left (PCS); LTC Franklin Smith will be the new Principal Investigator. The basic rationale for this project remains unchanged. Currently, this and other studies involving nonconsenting (minor) subjects in which no therapeutic benefit is expected for one arm of the study (control group) are under review by the OTSG. If the review is favorable, it is anticipated that this study will be picked up by a fellow in neonatology.

Detail Summary Sheet

Date: 9 Nov 84 Prot No: POG 8361(84) Status: Ongoing

TITLE: VP 16-213 and 5-Azacytidine in Combination For Refractory Acute Non-Lymphocytic Leukemia (ANLL), Phase II

Start Date: Jun 84		Est Comp Date: Indefinite
Principal Investigator: COL Stephen R. Stephenson, MC		Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology		Associate Investigators: MAJ Bruce A. Cook, MC CPT Dominic Solimando, MSC
Key Words: Leukemia, non-lymphocytic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in June 85

OBJECTIVE: Patients with ANLL under 21 years of age with disease refractory to standard drugs will be given a combination of non-standard drugs shown to be effective in pilot studies. The objective is to improve response in these patients.

TECHNICAL APPROACH: This phase II study will test whether increasing the dose of VP=16 will produce hypoplasia in two versus three courses and improve response.

PROGRESS: No TAMC patients have been entered as yet.

Detail Summary Sheet

Date: 9 Nov 84		Prot No: POG 8303(84)		Status: Ongoing	
TITLE: Combination Chemotherapy for First Bone Marrow and/or Testicular Relapse of Childhood Acute Lymphoblastic Leukemia (ALL) During or Shortly Following Initial Continuation Therapy (Simal 3), Phase III					
Start Date: Jun 84			Est Comp Date: Indefinite		
Principal Investigator: LTC Stephen R. Stephenson, MC			Facility: Tripler Army Medical Center		
Dept/Sec: Pediatrics/Hematology-Oncology			Associate Investigators: MAJ Bruce A. Cook, MC LTC M. Ordonez-Schneider, MC LTC Joseph Woods, MC CPT Dominic Solimando, MSC		
Key Words: Leukemia, acute lymphocytic					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost: \$300.		Periodic Review Results: To be reviewed in June 85	

OBJECTIVE: To determine the effectiveness of two aggressive induction regimens and two maintenance regimens in recurrent acute lymphocytic leukemia.

TECHNICAL APPROACH: All patients less than 21 years of age bone marrow or occult testicular relapse after three years of remission and patients with CNS relapse (on or off therapy) are eligible. Treatment will be as outlined in the protocol.

PROGRESS: No TAMC patients have been entered to date.

Detail Summary Sheet

Date: 30 Oct 84		Prot No: 37/83	Status: Completed
TITLE: Evaluation of Ruptured Thoracic Aorta Secondary to Blunt Trauma on Oahu			
Start Date: Aug 83		Est Comp Date: Sep 84	
Principal Investigator: CPT Ralph S. Carungi, MC		Facility: Tripler Army Medical Center	
Dept/Sec: Surgery		Associate Investigators:	
Key Words: Ruptured thoracic aorta			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,000.	Periodic Review Results: Completed	

OBJECTIVE: To evaluate cases of ruptured thoracic aorta secondary to blunt trauma on Oahu in the past five years.

TECHNICAL APPROACH: The data base of this retrospective review was from records of the Medical Examiner's Office of the City and County of Honolulu, Tripler Army Medical Center, The Queen's Medical Center, St. Francis Hospital, Straub Hospital, and Kaiser Hospital.

PROGRESS: Charts of patients who have sustained ruptured thoracic aortas presenting to TAMC during the past five years were reviewed. There was a total of five patients, with two being DOA, two dying of a delayed diagnosis, 5 hours and 74 days, and only one survivor. A manuscript is in preparation.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 16/83	Status: Completed
TITLE: Autologous Implants for Use in Reconstruction of Physical Deformities Involving the Head and Neck: Morphological Study with Clinical Application		
Start Date: Feb 83	Est Comp Date:	
Principal Investigator: CPT Dennis M. Everton, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Otolaryngology	Associate Investigators: LTC Michael Lepore, MC COL Donald Yim, MC	
Key Words: Autologous fascia grafts		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,500.	Periodic Review Results: Completed

OBJECTIVE: To determine the gross and histomorphologic changes of autologous fascia as it relates to time and place of grafting.

TECHNICAL APPROACH: Ten rabbits were utilized for the first phase of this study. Fascia was removed from the lateral aspect of the leg. The size (diameter) and weight (Mettler H-10 analytical balance utilized) was recorded. The tissue was then placed into the subcutaneous area of the abdomen and ear, and into the intraabdominal cavity. The tissue grafts were then removed at 1, 2, 3, and 4-month intervals. Again, the fascia grafts were weighed and the diameter recorded.

PROGRESS: The results show that weight loss was dramatic and size remained relatively stable. Histologic evaluation reveals that fascia had no inflammatory response present with the exception of the immediate areas of suture and necrotic muscle.

The results of this first phase of the study were presented at our national convention in Anaheim, California, October 1983, both by poster and oral presentation.

Everton DM, Lepore ML, Yim DWS, Quilligan JJ, Stacy CC, Van Sant T: Autologous Fascia Grafts in Head and Neck Plastic Surgery. Arch Otolaryngol 110:452-462, July 1984.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 5/83	Status: Ongoing
TITLE: Audiological Management Considerations of Known Ototoxic Drug Users		
Start Date: Nov 82	Est Comp Date: Sep 84	
Principal Investigator: LTC Jerod L. Goldstein, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Otolaryngology	Associate Investigators:	
Key Words: Ototoxic drug users		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: May 84/Continue

OBJECTIVE: To determine the sensitivity of ultra high frequency audiometry testing procedures compared to standard frequency audiometry for detection of ototoxicity from drugs.

TECHNICAL APPROACH: Threshold shift(s) of potential drug users over time will be measured utilizing ultra high frequency stimulus. A clinical procedure of high predictive value to detect the earliest reversible stage of ototoxicity will be designed.

PROGRESS: Progress on the above study has been delayed due to equipment failure. Equipment was recently returned from manufacturer. Calibration and possible data collection will begin soon.

Detail Summary Sheet

Date: 19 Dec 84	Prot No: 18H/84	Status: Completed
TITLE: Music: Method for Anxiety Reduction in the Operative Patient		
Start Date: May 84	Est Comp Date:	
Principal Investigator: CPT Penelope Henderson, ANC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Anesthesiology	Associate Investigators: CPT Larry Curtis ANC CPT Christine K. Booth, ANC CPT Dennis Hines, ANC CPT Michael Torposs, ANC	
Key Words: Anxiety reduction; music		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$346.	Periodic Review Results: Completed

OBJECTIVE: To investigate possible alternatives to medication as a method for reducing anxiety in the operative patient, thereby reducing the risk of possible side effects of the preoperative medications. The authors of this proposal have chosen to investigate music as that alternative.

TECHNICAL APPROACH: Patients were randomly assigned to one of four groups: Group I, preoperative medication; Group II, music; Group III, control group; and Group IV, music and medication. There were 16 subjects in each group. The medication groups received intravenous Valium. The music groups listened to classical music via headphones from a portable tape player. The subjects were tested for anxiety at three different points on the day of surgery, using the state-trait anxiety inventory. Their vital signs were also recorded at these times.

PROGRESS: Twenty-four patients were studied. There were no statistically significant group differences with respect to state anxiety levels. None of the physiologic parameters yielded significant differences. Thus the results of the statistical data support the hypotheses as stated: There is no difference between music and preoperative medication in the preoperative period. There is no difference between music and preoperative medication in the intraoperative period. The implications of this study are that neither music nor premedication decrease anxiety in a statistically significant manner. Our recommendation, therefore, is to avoid the use of premedication or music and, instead, utilize a good preoperative interview the day before the surgery in an attempt to allay a patient's fears and to explain to the patient what to expect.

Detail Summary Sheet

Date: 29 Oct 84	Prot No: 8A/84	Status: Ongoing
TITLE: An Experimental Proposal Using Animals to Study Gastrointestinal Staplings		
Start Date: Dec 83	Est Comp Date: Feb 84	
Principal Investigator: LTC Yeu-Tsu M. Lee, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/General Surgery	Associate Investigators: CPT William S. Stokes, VC Gordon H. Bryant	
Key Words: Gastrointestinal stapling		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$700.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To study the natural course and possible applications of completely stapling across the lumen of the gastrointestinal (GI) tract.

TECHNICAL APPROACH: (1) Iatrogenic penetrating injuries of the esophagus, duodenum, high and distal small intestine, and colon will be made and repaired. The suture lines will then be protected by having complete stapling across the lumen proximally. (2) The gastrointestinal content will be bypassed proximal to stapling lines with various gastrointestinal bypasses.

PROGRESS: From 1 Dec to 13 Dec 83, operations were performed on six rabbits. All animals were either dead or sacrificed by 15 Dec 83. From 1 Mar to 31 Aug 84, eight pigs were operated on. All animals were either dead or sacrificed by 18 Oct 84.

Detail Summary Sheet

Date: 30 Oct 84 Prot No: 25/78 Status: Terminated
 TITLE: Microvascular Training Protocol

Start Date: May 78		Est Comp Date: Indefinite
Principal Investigator: LTC Julio E. Ortiz, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/Plastic Surgery		Associate Investigators:
Key Words: Training, microvascular		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1000.	Periodic Review Results: Terminated

OBJECTIVE: To develop and maintain microvascular suture technique among the Plastic Surgery Service staff, TAMC, and to familiarize general surgery and other specialty residents with the techniques of microvascular anastomosis.

TECHNICAL APPROACH: To divide and reanastomose the common femoral artery and vein of rats. One pair of vessels per week with delayed evaluation of patency is planned. Later expansion to other models such as the rabbit ear and dog intestine and vas deferens is possible.

PROGRESS: This protocol has been terminated and replaced by protocol No. 2T/84.

Detail Summary Sheet

Date: 15 Nov 84	Prot No: 2T/84	Status: Ongoing
TITLE: Training Protocol for Microsurgery		
Start Date: Oct 83	Est Comp Date: Indefinite	
Principal Investigator: LTC Julio E. Ortiz, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Plastic Surgery	Associate Investigators:	
Key Words: Training, microsurgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1950.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To develop and maintain proficiency in microvascular anastomosis of veins, arteries, and nerves.

TECHNICAL APPROACH: The groin vessels of the rat or rabbit will be transected and reanastomosed using microvascular principles. The ears of the rabbit will be transected near its junction with the scalp and replantation attempted through microvascular techniques.

PROGRESS: LTC Ortiz is no longer assigned to TAMC. MAJ Stuart B. Kincaid, MC, will be the new principal investigator on this protocol.

Detail Summary Sheet

Date: 30 Oct 84 Prot No: 17/83 Status: Ongoing

TITLE: Relationship of Increased Intracranial Pressure in Primates with Dicrotic Notching on the Gee-OPG

Start Date: May 83		Est Comp Date:
Principal Investigator: LTC Thomas P. Perone, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/Neurosurgery		Associate Investigators: CPT William S. Stokes, VC John R. Claybaugh, Ph.D.
Key Words: Dicrotic notching		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2,000.	Periodic Review Results: Feb 84/Continue

OBJECTIVE: To determine if the Gee Oculopneumoplethysmography (Gee OPG) can be used as an accurate, noninvasive means of identifying increased intracranial pressure (ICP) in primates, and to set the groundwork for human experimentation using the Gee OPG as a noninvasive means of measuring increased ICP.

TECHNICAL APPROACH: Under general anesthesia, sterile saline was infused into the subarachnoid space and intracranial pressure measured through the infusing catheter. Intracranial pressure was increased incrementally to a maximum of 100 mms of mercury, and serial OPGs were performed.

PROGRESS: Ten attempts at this experiment have been made. However, because of technical problems, six of these attempts had to be aborted. Of the four successful attempts, the first was performed on an animal that was subsequently found to be diabetic and was discontinued from this study. The remaining three successful attempts have been performed on the same animal. In all of these, the intracranial pressure has varied between 8 mms of mercury and 100 mms of mercury for short periods of time, i.e., 5 minutes or less, and no dicrotic notch has been found on the OPG tracing. We have evaluated noninvasively the intraocular pressure associated with the OPG and have found that the intraocular pressure significantly increases immediately after the OPG and gradually decreases over a period of approximately 20 minutes to the baseline value. The presence or absence of the dicrotic notch in rabbits, pigs, and goats may be studied to see if one of these species is suitable for further study of this phenomenon.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 18/83	Status: Ongoing
TITLE: The Incidence of Dicrotic Notching on Gee-OPG in Patients with Defined Head Trauma or Tumors		
Start Date: Apr 83	Est Comp Date: June 84	
Principal Investigator: LTC Thomas P. Perone, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Neurosurgery	Associate Investigators: LTC Bernard Robinson, MC MAJ David W. Olson, MC	
Key Words: Dicrotic notching Gee-OPG		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine the incidence of patients with specific trauma/tumor to the head showing dicrotic notching on the Gee-OPG.

TECHNICAL APPROACH: In an attempt to identify a noninvasive method of measuring increased intracranial pressure, patients with clinically increased intracranial pressure due to trauma or brain tumors have an OPG performed by the vascular nurse. Excluded from this are patients with ocular trauma, ocular prostheses, or an absent globe. The OPG is a well-established, noninvasive device used in assessing cerebrovascular disease.

PROGRESS: Fifteen patients with various causes of increased intracranial pressure have been studied and we failed to see the dicrotic notch in a significant number. More significantly, however, is the maximal amplitude of the OPG, as well as the measurement of the slope of the OPG. These calculations are continuing.

Detail Summary Sheet

Date: 12 Jan 84	Prot No: 21/80	Status: Ongoing
TITLE: International Study on Lateral Electrical Stimulation for Treatment of Scoliosis		
Start Date: Jul 81	Est Comp Date:	
Principal Investigator: LTC Kent A. Reinker, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Orthopaedics	Associate Investigators:	
Key Words: Scoliosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$22,200.	Periodic Review Results: May 84/Continue

OBJECTIVE: To investigate the treatment of scoliosis in adolescents using stimulation of lateral musculature.

TECHNICAL APPROACH: Scoliosis of moderate degree in adolescent females has been treated recently with the use of electrical stimulation of the muscles using a 9-volt direct current with between 50 and 100 milliamperes of current. The muscles are stimulated to contracture at six second intervals while the patient is supine, usually asleep at night. Most stimulation is done during waking hours and the patients are encouraged to engage in perfectly normal activities during the daytime.

PROGRESS: Twenty-one TAMC patients have been treated with the electrical stimulator. Four patients have been treatment failures, three of which have required spinal fusion. The fourth is currently being treated in a standard brace program successfully. Six patients have successfully completed treatment; four more were successfully being treated at the time of transfer to participating mainland institutions. The remainder of patients are being treated successfully at present. The device has been deemed successful enough so that FDA approval has been given for the original device to be used for general use. However, early review of the device has led to significant modifications and improvements and the presently used device is still considered experimental because of these changes.

The results of this study were presented at the Society of Military Orthopaedic Surgeons meeting in November 1982.

Detail Summary Sheet

Date: 5 Dec 84 Prot No: 36/83 Status: Ongoing

TITLE: The Effect of Continuous Passive Motion on Intra-articular Trauma with Continuous Passive Motion Device (CPMD)

Start Date: Aug 83		Est Comp Date:
Principal Investigator: LTC Michael M. Romash, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/Orthopaedic		Associate Investigators: CPT Harald J. Henningsen, MC
Key Words: Intra-articular trauma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To assess the effect of continuous passive motion of joint function and rehabilitation after injury and/or repair of knee.

TECHNICAL APPROACH: Patients with intra-articular injuries of tibial plateau fractures, ruptured knee ligaments, reconstructed knee ligaments, patellar fractures, and dislocated patellae will be placed in the CPMD immediately after treatment. This will be done in a sequential fashion, alternating those so treated with those treated in the present fashion with early active motion or intermittent passive motion with no crossover. A total of 100 patients will be studied. The two groups will be compared regarding range of motion, need for narcotic medications, and bleeding, and will be followed for as long as possible for sequelae to their injury. If further surgery becomes indicated on the involved joint, inspection of cartilage will be accomplished. Rehabilitation parameters will also be measured, thigh girth, ability to weight-lift, and the range and timing of return to active duty or productive employment will be ascertained.

PROGRESS: Nothing has been accomplished as the equipment required for the study was never furnished through the Department of Clinical Investigation as required in the protocol. An adequate number of machines has been received piecemeal through routine hospital funds and we anticipate the start of the study this year.

Detail Summary Sheet

Date: 5 Dec 84 Prot No: 25H/84 Status: Ongoing

TITLE: Comparison of Braces in Anterior Cruciate Deficient Knees

Start Date: Sep 84		Est Comp Date:
Principal Investigator: ITC Michael M. Romash, MC		Facility: Tripler Army Medical Center
Dept/Sec: Surgery/Orthopedic		Associate Investigators: CPT Harald J. Henningsen, MC
Key Words: Knee braces Anterior cruciate deficient knees		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Sep 85

OBJECTIVE: To compare several available knee braces on the basis of knee function and patient preference in anterior cruciate deficient knees.

TECHNICAL APPROACH: Ten patients with unstable knees will be fitted with at least 7 various knee braces. A series of controlled exercise drills will be set up and used to assess patient function utilizing each brace. Times from each exercise will then be used to compare the patient's performance in each brace and without bracing. These exercises will be designed to test mobility, agility, and strength of the patient. Each patient will train on the course at his convenience. Braces will be issued to the volunteers in a random fashion.

PROGRESS: Patients and braces have been selected. A course for objectively testing these patients has been devised. The project is still awaiting determination of status of donation of braces.

Detail Summary Sheet

Date: 31 Dec 84	Prot No: 23A/84	Status: Ongoing
TITLE: The Effect of Indomethicin on Vasopressin Levels and Postobstructive Diuresis in a Conscious Goat Model		
Start Date: Feb 84	Est Comp Date: Mar 85	
Principal Investigator: CPT Bruce C. Stone, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Urology	Associate Investigators: John R. Claybaugh, Ph.D. Jill Sondeen, Ph.D. CPT William S. Stokes, VC COL Douglas Soderdahl, MC LTC William Kennon, MC	
Key Words: Postobstruction ADH, Prostaglandin inhibitor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,046	Periodic Review Results: Oct 84/Continue

OBJECTIVE: To determine if prostaglandin synthesis inhibition in the renal medulla during postobstructive diuresis improves the renal concentration defect and correlates with changes in vasopressin levels.

TECHNICAL APPROACH: Bilateral internal catheters are surgically placed under anesthesia. Baseline urine and blood samples are taken via intravenous lines. Ureters are then obstructed for 48 hours to induce a diuresis. Repeat urine and blood samples are taken. Indomethicin is administered intravenously before release of obstruction in one study arm.

PROGRESS: Technical problems occurred in four goats requiring termination from the study. Procedures were attempted in eight goats; four were successful. There is evidence for prostaglandin inhibition with Indomethicin; no evidence of ADH effect. There is an appropriate, if short, diuresis induced.

Detail Summary Sheet

Date: 31 Dec 84	Prot No: 13A/84	Status: Completed
TITLE: Aron Alpha A Cyanoacrylate Repair of Open Intra-articular Fractures in Mature Rabbits		
Start Date: May 84	Est Comp Date:	
Principal Investigator: LTC Lynnford S. Wilson, MC	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Orthopaedic	Associate Investigators: CPT William Stokes, VC	
Key Words: Intra-articular fractures		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: Completed

OBJECTIVE: To demonstrate an alternative to conventional metal fixation of these fractures using an adhesive.

TECHNICAL APPROACH: A fracture will be produced in the rabbit knee and either pinned or glued back together. Rabbits will be euthanatized and histopathology will be done to check bony restoration.

PROGRESS: Ten rabbits have been operated on and euthanatized. Histopathology specimens are currently being evaluated.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 19/83	Status: Ongoing
TITLE: Phase II Study of Human Interferons- α (HuIFN- α (Le)) in Patients with Nasopharyngeal Carcinoma (NPC) and Determination of the Effect of IFN on Epstein-Barr virus (EBV)-related Immunological Markers		
Start Date: Feb 84	Est Comp Date: Feb 87	
Principal Investigator: COL Donald W.S. Yim	Facility: Tripler Army Medical Center	
Dept/Sec: Surgery/Otolaryngology	Associate Investigators: Nathaniel Ching MD Thomas Lou, MD Kevin Loh, MD Meredith Pang, MD Clara Ching, MD Thomas Merigan, MD	
Key Words: Interferon- α Nasopharyngeal carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: Oct 84/Continue

OBJECTIVE: (1) To determine the objective response rate to HuIFN- α (Le) in patients with NPC. (2) To measure time and onset and duration of response. (3) To determine changes in EBV-related immunologic markers in response to IFN. (4) To determine clinical and laboratory factors that correlate with therapeutic activity. (5) To determine the toxicity of IFN in patients with NPC.

TECHNICAL APPROACH: Approximately 20 patients will be enrolled in the study who have received at least two weeks of treatment with (HuIFN- α (Le)). Approximately 10 patients will be entered from Hawaii. This Honolulu aspect of the study will be in collaboration with Dr. Thomas Merigan who is the principal investigator at Stanford University, and the interferon will be administered under his IND number for use of the investigational drug.

PROGRESS: This study received full approval at the SGO level in February 1984. One patient was entered on the study with special approval. No new patients have been enrolled.

REFERENCES: King NPH, Ching CY, Jim ELS, Loh KK, Oishi N, Yim DWS: The Natural Killer Cell-Interferon System in Human Carcinoma--Its Relation to Interferon Cancer Treatment Trials. Hawaii Med J 43(10):370-372, Jul 1984.

FEES: The interferon is provided gratis, value unknown.

Detail Summary Sheet

Date: 7 Nov 84		Prot No: 26D/84	Status: Ongoing
TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative			
Start Date: Aug 84		Est Comp Date: Indefinite	
Principal Investigator: CPT Dominic A. Solimando, Jr., MSC		Facility: Tripler Army Medical Center	
Dept/Sec: Pharmacy Service/Oncology		Associate Investigators: COL Jeffrey L. Berenberg, MC LTC Stephen R. Stephenson, MC MAJ Bruce A. Cook, MC MAJ William J. Uphouse, MC	
Key Words: Hyperuricemia Allopurinol			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$300.	Periodic Review Results: To be reviewed in Aug 85	

OBJECTIVE: To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

TECHNICAL APPROACH: This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 3-4 patients a year will be treated on this protocol.

PROGRESS: One patient has been entered and treated on the study. Report filed with Burroughs-Wellcome (study sponsor).

GIFTS: The allopurinol is provided gratis, value unknown.

Detail Summary Sheet

Date: 30 Oct 84	Prot No: 4H/84	Status: Completed
TITLE: Relation of Training to Umbilical Complication		
Start Date: Nov 83	Est Comp Date: Completed	
Principal Investigator: CPT Virginia B. Grayson, ANC	Facility: Tripler Army Medical Center	
Dept/Sec: Preventive Medicine Service	Associate Investigators:	
Key Words: Umbilical complication		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$500.	Periodic Review Results: Completed

OBJECTIVE: To determine if there is a significant decrease in neonatal umbilical cord complications if the mother attends prenatal classes.

TECHNICAL APPROACH: Data was collected by a structured questionnaire completed by the participants.

PROGRESS: The sample consisted of 141 mothers; however only 46 infants had information on umbilical reactions. Of the 141 mothers, 60 attended prenatal classes and 30 received cord care instruction. However, 91% of the 141 received cord care instructions on the ward before being discharged from the hospital. Only four mothers did not receive any type of training. There was not a significant decrease in neonatal cord reactions whether the mother attended prenatal classes or only had ward instruction. Additionally, there was not a significant difference in cord reactions associated with high versus low test scores, maternal age, desired pregnancy, race, mother's active duty rank, or husband's military rank. However, first birth versus two or more births was nearly significant ($3.669 \ 0.05 < P < 0.1$). A complicating factor of this study was that the infants' cords separated on the average of 12.3 days and were lost to observation when the infants were seen at the two-week Well Baby Clinic at an average age of 15.7 days.

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